





Approval Signature:	Date:
Approved By: Title:	
Approval Signature:	Date:

Approved By: Title:

VERSION HISTORY

Author	Author Revision		Change History
Steve Clark	1.0	01-Jun-2022	Document Creation

This controlled document is proprietary and is protected by U.S. and international copyright laws and trade secret laws. Copyright @ 2021 TransPerfect International, Inc. (TransPerfect). All rights reserved. No part of this document may be reproduced, copied, adapted, modified, distributed, transferred, translated, disclosed, displayed or otherwise used by anyone in any form or by any means without the express written authorization of TransPerfect Senior Management and/or Quality Assurance Department. Other names may be trademarks of their respective owners.



Table of Contents

1	Defi	Definitions/ Acronyms8						
2	Org	anizations	9					
	2.1	Pre-Requisites	9					
	2.2	Creating an Organization	9					
	2.3	Editing an Organization	11					
	2.4	Associating an Address to an Organization	13					
	2.5	Associating an Organization to a Parent Organization	14					
	2.6	Associating a Contact to an Organization	15					
	2.7	Reviewing Studies Associated to an Organization	16					
3	Spo	nsors	18					
	3.1	Pre-Requisites	18					
	3.2	Defining a Sponsor	18					
	3.3	Defining Sponsor Settings	19					
	3.4	Associating a Product to a Sponsor	20					
	3.5	Creating a Program for a Sponsor	21					
	3.6	Creating a Study for a Sponsor	22					
	3.7	Reviewing Sites for a Sponsor	23					
4	Con	tacts	24					
	4.1	Pre-requisites	24					
	4.2	Levels of Contact Creation in the Application	24					
	4.3	Creating a Contact	25					
	4.4	Editing a Contact at Domain, Site and Organization Levels	26					
	4.5	Editing a Contact	26					
5	Stud	dies	28					
	5.1	Pre-Requisites	28					
	5.2	Creating a Study2						
	5.3	Blinded Studies	29					
	5.3.	1 Adding Unblinded Personnel to a Blinded Study	29					
	5.4	4 Editing a Study						



	5.5	Entering Study Settings
	5.6	Defining Study specific Regions
	5.7	Editing Study Regions
	5.8	Defining and Editing Countries Within a Study
	5.9	Associating Organizations to a Study
	5.10	Defining Study Partners
	5.11	Associating Contacts to a Study40
	5.12	Creating Sites within a Study41
	5.13	Reviewing Subjects Within a Study42
	5.14	Study Sites Pre-Requisites
	5.15	Editing a Site in a Study43
	5.16	Tracking Informed Consents (ICFs) for a Site45
	5.17	Tracking Site Addresses47
	5.18	Associating an Organization to a site
	5.19	Change of Principal Investigator (PI)49
	5.20	Creating Site Visits
	5.21	Updating a Site visit
	5.22	Tracking Subjects
	5.23	Editing a Subject53
	5.24	Tracking Subjects Visits
	5.25	Editing a Subject Visit55
	5.26	Reviewing and Tracking Country Details56
	5.27	Tracking Country Informed Consents (ICFs)57
	5.28	Creating Site within a Country
	5.29	Associating an Organization with a Country59
	5.30	Associating Contacts with a Country60
6	Site	Visit Documentation
	6.1	Pre-Requisite
	6.2	Navigation to Site Visit61
	6.3	Site Visit Attendees
	6.4	Site Visit Locations



	6.5	Site Visit Activities	65
	6.6	Site Visit Subjects	66
	6.7	Site Visit Enrollment Summary	68
	6.8	Site Visit Confirmation Letter Creation	70
	6.9	Site Visit Draft Report Generation	71
	6.10	Site Visit Final Report Generation	73
	6.11	Site Visit Follow-up Letter Creation	73
7	Proc	duct	73
	7.1	Creating a Product	73
	7.2	Reviewing and Editing a Product	75
	7.3	Associating an Organization to a Product	77
	7.4	Associating a Contact to a Product	77
8	Prog	gram	78
	8.1	Pre-Requisites	78
	8.2	Create a Program	78
	8.3	Reviewing and Editing a Program	80
	8.4	Associating an Organization to a Program	82
	8.5	Associating a Contact to a Program	82
	8.6	Associating a Product to a Program	84
9	Acti	vities	84
	9.1	Associating Domain library Activity Records to a Study	84
	9.2	Creating Domain library Activity Records	86
	9.3	Editing Domain Library Activity Records	87
	9.4	Deleting Domain Activity Records	88
	9.5	Inactivating Domain Activity Records	89
	9.6	Creating Domain Library Activity Plans	90
	9.7	Editing Draft Activity plans	92
	9.8	Publishing Activity Plans	93
	9.9	Retiring Activity Plans	94
	9.10	Copying Activity Plans	95
	9.11	Associating Activity Plan Templates to a Study	96



9.	12	Scheduling Activity Plans	97
9.	13	Tracking Activities Outside of Activity plans	
10	N	1ilestones	
10).1	Pre-Requisites	102
10).2	Creating Domain Library Milestone Template	
10).3	Creating a Study Milestone from a Template	103
10).4	Editing Domain Milestone Templates	105
10).5	Deleting Domain Milestone Templates	105
10).6	Publishing Milestone Templates	106
10).7	Retiring Milestone Templates	107
10).8	Copying Milestone Templates	
10).9	Associating Milestone Templates to a Sponsor	109
10	0.10	Defining Sponsor-Specific Milestone Templates	111
10).11	Defining Study Milestone Templates (New)	113
10).12	Tracking Milestones	117
11	D	ashlets	117
11	1	The Portfolio Dashlet	117
11	2	The Top Countries Dashlet	118
11	3	The Studies Dashlet	119
11	4	The CRA Visit Report Performance Dashlet	120
11	5	Reviewing Studies via their Dashboard	121
11	6	Reviewing Countries via their Dashboard	123
11	7	Reviewing Site Dashboard	124
12	U	lser and Team Management	126
12	2.1	Creating Users	126
12	2.2	Editing a User	127
12	2.3	Editing a User's Permissions	128
12	2.4	Study Team Management	130
12	2.5	Deactivating a User Account	130
12	2.6	Resending a User's Invite	131
12	2.7	Removing Users from a Team list	



Version 1.0 Page 7 of 130

1 Definitions/ Acronyms

Term/ Acronym	Explanation	Definition		
CTMS	Clinical Trial Management System	An application used as a centralized location to manage clinical trial data.		
CSM	Clinical Study Manager	A key clinical study team member that assists in the conduct of clinical trial activities in accordance with all applicable regulations governing the conduct of clinical trials.		
CRA	Clinical Regulatory Associate	A CRA is a clinical study team member that monitors the progress of investigators in a clinical study.		
ICF	Informed Consent Form	An ICF is used to ensure everyone involved in clinical research is a willing participant, with full knowledge of the potential risks and benefits to the extent that is possible.		

2 Organizations

T R I A L INTERACTIVE

2.1 Pre-Requisites

Company administrators will need to assign CREATE, UPDATE, EDIT and DELETE permissions/privileges to users' accounts so that they can perform these steps.

2.2 Creating an Organization

- 1. Click on the organization link in the Navigation Menu in the panel at the left side of the screen.
 - a. This opens the "Organization" window, and all the organizations at the domain level are displayed.

	*	Organizations						[Search Q AA
	«		Org	anizations					
		F	O A	dd 🧪 Edit 💿 Activate	🗐 Delete				Q Search Tilters
		\mathcal{O}	122 0	organizations					
		TrialInteractive		Name	Status	Parent Organization	Туре	Subtype	Primary Contact
				j&j	Active		Hospital		
	6 20	Dashboard		ARI	Active		Partner		
		Sponsors		China Holding Corp	Active		Partner		
		Programs		Central Lab of China	Active		Lab		
	<u>е</u> д	Products Studies		Jiahui International Hospital	Active		Hospital		
		Organizations		Astroville Corporation	Approved		Pharmaceutical Company		
		Contacts		Dermeron	Active		Sponsor		
		User Management Activities Library		Vickie and Jack Farber Insti	Active	Thomas Jefferson Universi	Investigative Site	Local	
		Activity Plan Templates		Thomas Jefferson Universi	Active	Thomas Jefferson University	Hospital	Local	
	9	Milestone Templates		Thomas Jefferson University	Active		University	Local	
				Scotts Labels	Active		Partner		
				Scott Works	Active		Sponsor		🛔 Jordan Martin
≡				Sydney Neurology	Active		Clinic	Central and local	
٠									
E									Previous 1 of 10 Next

- 2. Click the **Add** button at the top-left of the screen.
 - a. This opens the "Create Organization" window.
- Here we need to enter the mandatory metadata to create an organization i.e., Name, Number, Type and Status as indicated by an asterisk (*) symbol next to the field title. Enter any additional information, as necessary.
- 4. If any of the required fields are missing, an error will appear when we click on the **Create** button displaying the fields which need to be filled to create an organization successfully.

This document is proprietary and is protected by U.S. and international copyright laws and trade secret laws. Copyright © 2021 TransPerfect International, Inc. (TransPerfect). All rights reserved. No part of this document may be reproduced, copied, adapted, modified, distributed, transferred, translated, disclosed, displayed or otherwise used by anyone in any form or by any means without the express written authorization of TransPerfect Senior Management and/or Product Management. Other names may be trademarks of their respective owners.

TI CTMS USER GUIDE v1.2

	*	Organizations			[Search Q AA -
	«	\sim	Organization Create Organization			
		To	General Information		Press F1	1 to exit full screen
			122 Organizations			G
		TrialInteractive	Name J8j		Subtype	Primary Contact
			ARI			
	2 2	Dashboard	Parent Organization			
		Sponsors Programs				
		Products	Central Lab of Cl Type* Subtype			
	즈	Studies	Jiahui Internation			
		Organizations	Astroville Corpo	any		
	**	Contacts	Dermeron Primary Contact			
		User Management Activities Library	Vickie and Jack F		Local	
		Activity Plan Templates	Thomas Jefferso Phone Numbers		Local	
	8	Milestone Templates	Thomas Jefferso • Add		Local	
			Scotts Labels Notes			
			Scott: Works			🛎 Jordan Martin
=			Sydney Neurolog		Central and local	
٠			Cancel Select and Add Another Create			
C						♦ Previous 1 of 10 Next

5. **(Optional)** Click on the **Add** symbol below **Phone Number** to add a contact number to that organization.

Note: When creating an organization record with at least one phone number, you will need to designate one phone number as the primary number.

6. **(Optional)** Click **Include Address,** select a type for the address, and enter the address information.

Note: The Search functionality can be utilized to search for addresses.

- 7. Finally, before clicking **Create**, verify all the fields are entered correctly in the Create Organization window.
- 8. Click **Create** or **Select and Add Another** depending on whether you intend to create another organization right away.

TI CTMS USER GUIDE v1.2

	#	Organizations				Search Q AA -
	«			Create Organization		
		Fa	🕒 Add	Phone Numbers O Add		Q Search Tilters
			122 Org		Subtype	Primary Contact
		TrialInteractive				
	<i>6</i> 20	Dashboard Sponsors				
		Programs Products		tra		
	<u>⊥</u>	Studies Organizations		Include Address C		
	**	Contacts User Management		Address Type*		
		Activities Library Activity Plan Templates		Search Q. Enter address and press Return	Local	
	8	Milestone Templates		Primary Address®	Local	
				Address Line 2		🛔 Jordan Martin
≣				Advance line 3	Central and local	
*				ntre Cancel Select and Add Another Create	Local	
E						Previous 1 of 7 Next

2.3 Editing an Organization

- Click on the **Organizations** link in the Navigation Menu in the panel at the left side of the screen.
 a. This opens the "Organization" window.
- 2. Click on the checkbox next to the organization name.
 - a. A quick-view panel will display on the right side of the screen.
- 3. Now, click on the **Edit** button (pencil icon).
- 4. Make any necessary changes.
- 5. Click on the **Save** button to apply the changes.

TI CTMS USER GUIDE v1.2

	*	Organizations		Search Q AA -
	«	\sim	Organizations	
		F	Add Activate B Delete	Q Search Tilters
		\mathcal{O}	122 Organizations 1 Selected	Astroville Corporation
		TrialInteractive	Name Status Parent Organizati Type Subtype Primary Contact	AC Approved 08 Sep 2021
			Bij Autor Hospital	
	1	Dashboard	ARI Axve Partner China Holding Axve Partner	Organization Information
		Sponsors Programs		Number Status 1247982021 Approved
		Products Studies		Name
	U	Organizations	Astroville Corpo Approved Pharmaceutical	Astroville Corporation
	**	Contacts User Management	Dermeron Attive Sponsor	Parent Organization
		Activities Library	Vickie and Jack Active Thomas Jeffers Investigative Site Local	Type Subtype
		Activity Plan Templates	Thomas Jeffers Acove Thomas Jeffers Hospital Local	Pharmaceutical Compa
	9	Milestone Templates	Thomas Jeffers Active University Local	Description
			Scotts Labels Active Partner	
			Scott Works Active Sponsor & Jordan Martin	
			Sydney Neurolo Astre Clinic Central and local	Notes
٠			Day & Day Ship Attve Partner	
~			Montreal Neur McGill Universit Investigative Site Local	
C			Previous 1 of 7 Next >	

6. **(Optional)** Clicking on the organization name will open the "Organization Details" page. Editing an organization may also be done on the organization details page.

	Organization Central Lab of China	rganization Details	Search Q AA -
	«	Central Lab of China	Acce Press F11 to exit full screen 9 Edit History
	Central Lab of China Image: Contraction Details Image: Studies Image: Studies Image: Related Organizations Image: Contacts	Organization Information Number Status Description Name Central Lab of China Parent Organization Type Subtype Notes	0
		Contact Information	0
* C		Additional Information	G



2.4 Associating an Address to an Organization

- Click on the **Organizations** link in the Navigation Menu in the panel at the left side of the screen.
 a. This opens the "Organization" window.
- 2. Locate the organization to which you want to associate an address and click on the organization's name.
 - a. This opens "Organization Details" window.
- 3. Click the **Edit** button in the Organization window.
- 4. Click on the [+] sign next to Contact Information to expand that section.
- 5. Click on the **Add** button in the **Addresses** section.
 - a. This opens the "Add Address" window.
- Here we need to enter the mandatory metadata to create an address i.e., Address Type,
 Primary Address, Country, and Postal Code which have an asterisk (*) symbol next to the field title. Enter any additional information, as necessary.

Note: The Search functionality can be utilized to search for addresses.

7. If any of the required fields are missing, an error will appear when we click on the **Add Address** button displaying the fields which need to be filled to create an address successfully.

	ARI - Organization	nization Details	Search Q A -
	«	ARI	Active
		► Expand All Add Address ■ ★	S Edit History
	ARI	Organization Info	æ
		Contact Informati	•
	Organization Details Studies Sites	Q. Enter address and press Return Primary Contact Primary Address*	
	 Related Organizations Contacts 	Address Line 2	
		View All Contacts Town/City Province/State	
		Addresses Country* Postal Code*	
≣		Phone Numbers	
÷			
C		Additional Information	Ē

8. (Optional) Click Add and Create Another if you intend to create another address right away.

This document is proprietary and is protected by U.S. and international copyright laws and trade secret laws. Copyright \bigcirc 2021 TransPerfect International, Inc. (TransPerfect). All rights reserved. No part of this document may be reproduced, copied, adapted, modified, distributed, transferred, translated, disclosed, displayed or otherwise used by anyone in any form or by any means without the express written authorization of TransPerfect Senior Management and/or Product Management. Other names may be trademarks of their respective owners.

2.5 Associating an Organization to a Parent Organization

- 1. Click on the **Organizations** link in the Navigation Menu in the panel at the left side of the screen.
 - a. This opens the "Organization" window.

T R I A L INTERACTIVE

- 2. Click on the Name for any non-sponsor organization record from the list displayed.
 - a. This opens the "Organization Details" window.

	Organization Farmacia merulana dei dottori g	gue 🗸 Organizati	n Details		Search Q 🗛 🗸
	*	🖋 Edit 🛛 🛛 Expand All	erulana dei dottori guerra & del pio on Information	o snc >	्रस्वक © Edit History
	dei dottori guerra & del pio snc i Organization Details ii Studies iii Studies iiii Related Organizations iiiiiiiiiiiiiiiiiiiiiiiiiiiiiiiiiiii	Type Pharmacy	Number Status 3275262021 Active Name Farmacia merulana dei dottori guerra & del pio snc Parent Organization Farmacia Internazionale Subtype	Description Notes	
=		Contact In Additional	formation		Ũ
° C					

- Click the Edit button in the "Organization Detail" window, within the Parent Organization field select a parent organization.
- 4. Click the **Save** button.
- 5. The association can be verified by navigating to the Related Organizations area for the selected parent organization. (See the screenshot below)

This document is proprietary and is protected by U.S. and international copyright laws and trade secret laws. Copyright © 2021 TransPerfect International, Inc. (TransPerfect). All rights reserved. No part of this document may be reproduced, copied, adapted, modified, distributed, transferred, translated, disclosed, displayed or otherwise used by anyone in any form or by any means without the express written authorization of TransPerfect Senior Management and/or Product Management. Other names may be trademarks of their respective owners.

TI CTMS USER GUIDE v1.2

	#	 Organization Farmacia Internazionale 	Related Organizations				Search	Q	AA -
	*		Related Organizations						
			🕒 Add 🥒 Edit 🛛 🕄 Remove				Q Search		T Filters
		Farmacia	2 Organizations						G
		Internazionale	Name	Status	Parent Organization	Туре	Subtype		Primar P
			Farmacrimi	Active	Farmacia Internazionale	Pharmacy			
	i	Organization Details	Farmacia merulana dei dottori guerra & del pio snc	Active	Farmacia Internazionale	Pharmacy			
	<u> </u>	Studies							
		Sites Related Organizations				2			
	200	Contacts							
٠									
T									
6									

2.6 Associating a Contact to an Organization

- 1. Click on the **Organizations** link in the Navigation Menu at the left side of the screen.
 - a. This opens the "Organization" window.
- 2. Click on the **Name** of any organization record in the list.
 - a. This opens the "Organization Details" window.
- Click on the Contacts link in the Navigation Menu in the panel at the left side of the screen.
 a. This opens the "Create Contact in Organization" window.
- 4. Click Add and enter the required contact details.
- 5. Click Create.

TI CTMS USER GUIDE v1.2

	 Organization Jiahui International Hospital 	Contacts		Search Q	•
	 Jiahui International Hospital 	Contacts Add Edd I Contacts Name Anne Contacts Co	Create Contact in Organization X Ca. Search for Contacts General Information Prefix First Name* Middle Name	Q. Search Email Phone Lee@email.com	O OPEN
	Organization Details Suddes Suddes Sites Related Organizations Contacts		Last Name* Suffix job Title Contact Type* Email Address* Status* Active Phone Numbers • Add Include Address •		
≡ \$			Cancel Create and Add Another Create		
C					

2.7 Reviewing Studies Associated to an Organization

- Click on the **Organization** link in the Navigation Menu at the left side of the screen.
 a. This opens the "Organization" window.
- 2. Click on the organization's name in the list.
 - a. This opens the "Organization Details" window.
- 3. Click on the **Studies** link in the Navigation Menu at the left side of the screen.
 - a. This opens the "Studies" window.
- 4. The list of studies is displayed.

TI CTMS USER GUIDE v1.2

		Organizations				Search	<u>a</u>
	× ک	Organizations			à	Q Search	▼ Filters
	KingDerm1	1 Organizations					ntact PE
		Name King Trucking and Distribu		Parent Organization King Research	Type Su Supplier	ibtype Primary Co	ntact
■ • ℃	 Study Details Dashboard Milestones Countries Sites Subjects Organizations Contacts Team Activities Activity Plans 						
6	Organization King Trucking and Distribution +	Studies				Search	
	«	Studies					
		🥒 Edit				Q Search	T Filters
	King Trucking and	1 Studies Name Protocol N	umber Status	Sponsor Program	n Phase	Therapeutic Are # Planned Trial	# Planned Subje
	Distribution	KingDerm1 K001-1119		King Research	11-111	100	1000
≡	Organization Details Studies Stes Related Organizations Contacts			\$			
T							

3 Sponsors

3.1 Pre-Requisites

Users creating or managing **Sponsors** in an organization should have **CSM** user access. Company administrators will need to assign CREATE, UPDATE, EDIT and DELETE permissions/privileges to users' accounts so that they can perform these steps.

3.2 Defining a Sponsor

- 1. Click on **Sponsors** link in the Navigation menu at the left side of the screen.
 - a. This opens the "Sponsors" window, and Sponsors list is displayed.

 Sponsors						Search Q AA
	Sponsors					
F	🔷 Add 🛛 🥒 Edit 💿 Activate	Delete				Q Search Tilte
\mathcal{O}	33 Organizations					
TrialInteractive	Name	Status	Parent Organization	Туре	Subtype	Primary Contact
	Dermeron	Active		Sponsor		
Dashboard	Scott Works	Active		Sponsor		🛔 Jordan Martin
Sponsors	Myzer Rx	Active		Sponsor		
Programs	Waxo Smyth Clean Products	Active		Sponsor		
Products	Wayer Pharmaceuticals	Active		Sponsor		
Organizations	Acme Pharmaceuticals	Active		Sponsor		
Contacts	Sangra Drugs	Active		Sponsor		
User Management	RK Meds	Approved	Work Anywhere	Sponsor		
Activity Plan Templates	Wiser Meds	Approved		Sponsor		
Milestone Templates	Takeda Pharmaceutical Co. Ltd	Approved		Sponsor		
	Mari Tech	Activo		Sponsor		
	B-Ready Medicine	Active		Sponsor		
	A+ Drugs	Active		Sponsor		
	Acme Drugs	Active		Sponsor		
	Best Meds	Inactive		Sponsor		
	Working 4U	In Review		Sponsor		
	Winning World Medicine	Do not use		Sponsor		
	King Research	Approved		Sponsor		
	ACI Pharmaceuticals	Active	ACI Limited	Sponsor		
	ACI Limited	Active		Sponsor		
						Previous 1 of 2 Next

- 2. Click the **Add** button in the top-left of the screen.
 - a. This opens the "Create Sponsor" window.
- Here we need to enter the mandatory metadata to create a sponsor i.e., Name, Number, Type, Status, as indicated by an asterisk (*) symbol next to the field title. Enter any additional information, as necessary.
- 4. If any of the required fields are missing, an error will appear when we click on the **Create** button, displaying the fields which need to be filled to create a sponsor successfully.
- 5. **(Optional)** Click on the **Add** button in the **Phone Number** area to add a contact number to that sponsor.



- **Note**: When creating a contact record with at least one phone number, you will need to designate one phone number as the primary number.
- 6. **(Optional)** Click **Include Address**, select a type for the address, and enter the address information.

Note: The Search functionality can be utilized to search for addresses.

- 7. Finally, before clicking **Create**, verify all the fields are entered correctly in the create sponsor window.
- 8. Click **Create** or **Select and Add Another** depending on whether you intend to create another sponsor right away.
 - a. After clicking **Create**, the "Create Sponsor" window will close, and the sponsor record will be displayed in the list.

	*						•
	•	\sim	Sponsors				
		\mathcal{A}_{α}	💽 Add 🥒 Edit 🗢 Activate 🛞 Delete				T Filters
		\bigcirc	33 Organizations	e Sponsor 🛛 🗖 🗙			0
		TrialInteractive	Name Statu	1	Subtype	Primary Contact	OPEN
				Information			
	20	Dashboard	Scott Works			🛔 Jordan Martin	
		Sponsors	Myzer Rx Number*				
			Waxo Smyth Clean Products				
	Ā	Studies	Wayer Pharmaceuticals Parent Org				
		Organizations	Acme Pharmaceuticals	×			
		Contacts User Management	Sangra Drugs Ast Type*	Subtype			
		Activities Library	KK Meds				
		Activity Plan Templates	Wiser Meds Ap	~			
	8	Milestone Templates	Takeda Pharmaceutical Co. Ltd Primary Co Mari Tech Acti				
				۵			
			Phone N	imbers			
			Arme Drugs				
			Notes	B I U S			
			Working 4U				
			Winning World Medicine				
			King Research App	Cancel Select and Add Another Create			
=			ACI Pharmaceuticals Active	ACI Limited Sponsor			
			ACI Limited Active	Sponsor			
٠							
T						Previous 1 of 2	Novel 1
						Previous 1 of 2	vext P

3.3 Defining Sponsor Settings

- 1. Click on **Sponsors** link in the Navigation menu in the panel at the left side of the screen.
 - a. This opens the "Sponsors" window, and the Sponsors list is displayed.
- 2. Navigate to the sponsor's name you want to edit and click on it.
 - a. This opens "Sponsor Details" window.
- 3. Click on the **Settings** button in the top-right of the screen.



- a. This opens Sponsor settings window Milestone Templates screen.
- 4. Click on the milestone you want to edit.
 - a. This opens Edit Milestone Template window.
- 5. Make any necessary changes required in the Edit Milestone Template window.
- 6. Click **Save** for the changes to apply.

	At Drugs 👻 Sponsor St	ettings Milestone Templates				Search Q 🗛 🗸
	•	Milestone Templates				
		🖸 Add 🗸 📝 Edit 📋 Delete	Ø Set to Retired ♦ Publish 🖺 Copy			Q, Search Titters
	A+ Drugs	Edit Milestone Temp	late		Step 1 🔹 🗖 🗙	Sort By Unknown -
		General Information	General Information			🛱 Site
	Milestone Templates		Level*			Updated 08 Sep 2021 admin admin
			Template Name*	Classification		🛱 Site
			Last Subject Last Visit	Enroliment ×		Updated 08 Sep 2021 admin admin
			Description			
						🛱 Site
						Updated 08 Sep 2021 admin admin
						<u> </u> Study
						Updated 08 Sep 2021 admin admin
						👗 Study
						Updated 08 Sep 2021 admin admin
						👗 Study
						Updated 08 Sep 2021 admin admin
			Cancel	Save		
		Manual				A Study
						Updated 08 Sep 2021 admin admin
٠		Draft Regulatory				👗 Study
T		Manual V 1st Eti	hics Approval (Site)			Updated 08 Sep 2021 admin admin
0						

3.4 Associating a Product to a Sponsor

- 1. Click on **Sponsors** in the Navigation menu at the left side of the screen.
 - a. This opens the "Sponsors" window, and the list of sponsors is displayed.
- 2. Click on the name of the sponsor to which you want to associate a product.
 - a. This opens the "Sponsors Details" window.
- Click on the **Products** link in the Navigation menu at the left side of the screen.
 a. This opens the "Product" window.
- 4. Click on the **Add** button at the top-left of the screen.
 - a. This opens "Create Product" window.
- Here we need to enter the mandatory metadata to create a product i.e., Product Name, Type, Status, Status Date, Sponsor as indicated by an asterisk (*) symbol next to the field title. Enter any additional information, as necessary.

This document is proprietary and is protected by U.S. and international copyright laws and trade secret laws. Copyright © 2021 TransPerfect International, Inc. (TransPerfect). All rights reserved. No part of this document may be reproduced, copied, adapted, modified, distributed, transferred, translated, disclosed, displayed or otherwise used by anyone in any form or by any means without the express written authorization of TransPerfect Senior Management and/or Product Management. Other names may be trademarks of their respective owners.



- 6. If any of the required fields are missing, an error will appear when we click on the **Create** button, displaying the fields which need to be filled to create a product successfully.
- 7. **(Optional)** Click **Create** or **Create and Add Another** depending on whether you intend to associate another product to this sponsor immediately.

	*	A+ Drugs - Products							Search Q	AA •
	•									
			🖸 Add 🥒 Edit							T Filters
		A+ Drugs	1 Products							
			Product	Programs		Туре	Modifier	Owner	Sponsor	
			Diagnova	💰 Diagno	Create Product	- ×	System system	👗 Steven Clark	A+ Drugs	
		Sponsor Details Programs			Product Name*					
	Ê	Products				~				
		Studies			Status* Status Date* 20 Sep 202					
		Organizations Contacts			Sponsor*					
		Contacts			A+ Drugs					
					Select					
					Description					
							1			
					Cancel Create and Add Another	Create				
=										
-=										
۰										
T										

3.5 Creating a Program for a Sponsor

- 1. Click on **Sponsors** link in the Navigation menu in the panel at the left side of the screen.
 - a. This opens the "Sponsors" window, and the list of Sponsors is displayed.
- 2. Click the name of the sponsor to be associated with the new program.
 - a. This opens "Sponsor Details" window.
- 3. Click on the **Programs** link in the Navigation menu at the left side of the screen.
 - a. This opens the "Program" window.
- 4. Click on the **Add** button in the top-left of the screen.
 - a. This opens the "Create Program" window.
- Here we need to enter the mandatory metadata to create a program i.e., Program Name, Number, Status, Status Date, Sponsor, Products as indicated by an asterisk (*) symbol next to the field title. Enter any additional information, as necessary.
- 6. If any of the required fields are missing, an error will appear when we click on the Create button, displaying the fields which need to be filled to create a program successfully.

This document is proprietary and is protected by U.S. and international copyright laws and trade secret laws. Copyright © 2021 TransPerfect International, Inc. (TransPerfect). All rights reserved. No part of this document may be reproduced, copied, adapted, modified, distributed, transferred, translated, disclosed, displayed or otherwise used by anyone in any form or by any means without the express written authorization of TransPerfect Senior Management and/or Product Management. Other names may be trademarks of their respective owners.



7. **(Optional)** Click **Create** or **Create and Add Another** depending on whether you intend to create another program right away.

	*	A+ Drugs - Programs					Search Q. (A)	
	*		Programs					l
			🖸 Add 🥒 Edit				Q Search Titters	l
		A+ Drugs	2 Programs Program Name		_	Sponsor	Product	
			Diagnova321	Create Program	• *	At Drugs	2	
		Sponsor Devails Programs Products Starts Organizations Contacts	A+008	Pergram Kama* Series* Description Description		A + Drugs	<u>2</u>	
				Cancel Create and Add Another Create				
•								
T								
6								

3.6 Creating a Study for a Sponsor

- 1. Click on **Sponsors** in the Navigation menu at the left side of the screen.
 - a. This opens the "Sponsors" window, and the Sponsors list is displayed.
- 2. Click on the name of the sponsor for the new study.
 - a. This opens "Sponsor Details" window.
- 3. Click on **Studies** in the Navigation menu at the left side of the screen.
 - a. This opens the "Study" window, and the Studies list is displayed.
- 4. Click on the **Add** button in the top-left of the screen.
 - a. This opens the "Create Study" window.
- Here we need to enter the mandatory metadata to create a study i.e., Protocol Number, Study Name, Protocol Title, Status, Status Date, Primary Product, Phase, Design as indicated by an asterisk (*) symbol next to the field title. Enter any additional information, as necessary.
- 6. If any of the required fields are missing, an error will appear when we click on the **Create** button, displaying the fields which need to be filled to create a Study successfully.

Note: Sponsor field is already populated with the name of the sponsor you are working with.

This document is proprietary and is protected by U.S. and international copyright laws and trade secret laws. Copyright © 2021 TransPerfect International, Inc. (TransPerfect). All rights reserved. No part of this document may be reproduced, copied, adapted, modified, distributed, transferred, translated, disclosed, displayed or otherwise used by anyone in any form or by any means without the express written authorization of TransPerfect Senior Management and/or Product Management. Other names may be trademarks of their respective owners.



	_										
	*	A+ Drugs - Studies									a 🗛 -
	•										
			O Ac	dd 🥒 Edit							Tilters
		A+ Drugs	5 Stu	dies				_			
		A. Drugs		Name	Protocol Number	Create Study		• × •	Therapeutic Area(s)	# Planned Trial Sites	# Planned Subjects
				Diagnova	00123	Sponsor*				1	5
	i	Sponsor Details		Test1	001	A+ Drugs		- 10		5	50
				Downton Now	B215302	Protocol Number*	Study Name		Unknown	0	0
		Products Studies		AMed42021	8066142021			0		0	0
		Sites		Tremors Study	1052618-2021	Protocol Title*		_		0	0
		Organizations									
	- 20	Contacts									
						Types 0 Types Select		_ 1			
						Owner					
						admin admin		- 11			
						Status* Planned 0 V	Status Date*				
						Program	Primary Product*	_			
						v V		~			
						Cancel	Create				
=											
۰											
T											
0											

3.7 Reviewing Sites for a Sponsor

- 1. Navigate to the Home and click on the **Sponsors** link in the Navigation menu at the left side of the screen.
- 2. Click on the name of the sponsor.
 - a. This opens the "Sponsor Details" window
- 3. Click on the **Sites** in the Navigation menu at the left side of the screen.
 - a. This opens the "Sites" window



A Drugs - Site	5					Search Q 🗛
<.	Sites					
	All Sites Active Closed					
A+ Drugs	🥒 Edite					Q Search T Filte
	9 Sites					
	Name	Status	Organization	Investigator	Region	Completed Milestone
Sponsor Details Programs	📄 🙆 201 - Alam	New	Vickie and Jack Farber Institute for Ne	🛔 Shaista Alam	M Americas	HE PSSV
Products	2 101 - Pollard	New	Sydney Neurology	🛔 John Pollard	Dceania	
🚊 Studies	🔲 🖄 001 - Vieira	New	Montreal Neurological Institute-Hospi	🛎 Lucy Vieira	🛤 Americas	
Sites	(1) Jones - 002	New	A+ Drugs	A Berbare Jones		
Contacts	() Jones - 001	New	A+ Distributors	A Barbara Jones		
	(D) Joe	Active	A+ Drugs	Alison Foster		
	ABC Matry	Active	A+ Distributors	Ab DE		
	Cusick622	New	Metro Hospital North	A Vincent Cusick		
	() () Paul96	New	General Medicine Clinic of Tulsa	🛔 Linda Paul		

4 Contacts

4.1 Pre-requisites

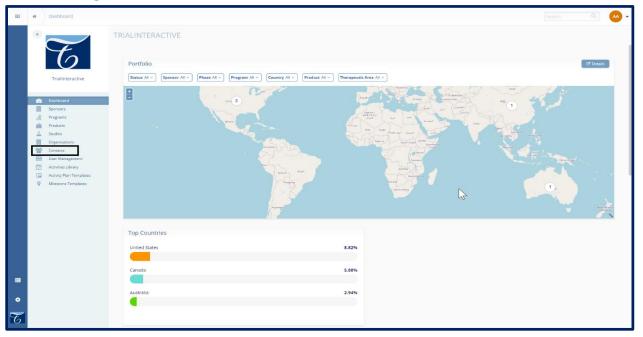
Each organization will need to decide who should create Contacts. It may be a specific group of people in the organization who are assigned to handle this to reduce the chances of creating duplicate records. Company administrators will need to assign CREATE, UPDATE, EDIT and DELETE permissions/privileges to user's accounts to that they can perform this step.

4.2 Levels of Contact Creation in the Application

There are multiple levels of creating and managing a contact, one is at the Domain Level, if a contact is created at Domain level it can be accessed and used anywhere in the system. The other way of creating and managing a contact is at their respective sub level (Site, Organization, Product, etc.). Contacts may be used at the level at which they are created as well as any lower levels of the data hierarchy.



4.3 Creating a Contact



- 1. Navigate to the appropriate level in the data hierarchy (i.e., Domain, Study, Site).
- 2. Click on the **Contact** link in the Navigation menu at the left side of the screen.
 - a. This opens the "Contact" screen.
- 3. Click on the **Add** button at the top-left of the screen.
 - a. The "Create Contact" window is opened.
- Here we need to enter the mandatory metadata to create a contact i.e. First Name, Last Name, Email Address and Status which have an asterisk (*) symbol next to the field title. Enter any additional information, as necessary.
- 5. If any of the required fields are missing, an error will appear when we click on the **Create** button and it displays the fields which need to be filled to create a contact successfully.
- 6. **(Optional)** Click on the **Add** symbol below **Phone Number** to add a contact number to that person.

Note: When creating a contact record with at least one phone number, you will need to designate one phone number as the primary number.

7. **(Optional)** Click **Include Address**, select a type for the address, and enter the address information.

Note: The Search functionality can be utilized to search for addresses.

This document is proprietary and is protected by U.S. and international copyright laws and trade secret laws. Copyright © 2021 TransPerfect International, Inc. (TransPerfect). All rights reserved. No part of this document may be reproduced, copied, adapted, modified, distributed, transferred, translated, disclosed, displayed or otherwise used by anyone in any form or by any means without the express written authorization of TransPerfect Senior Management and/or Product Management. Other names may be trademarks of their respective owners.

TI CTMS USER GUIDE v1.2

	# Contacts				Search Q A +
		Contacts	Create Contact		Q Search
	6	110 Contacts	General Information Prefix First Name* Middle Name		•
	TrialInteractive	Name	Zhang	Email Jae®email.con	Phone
	Deshboard	🛔 Eun He Lea	Last Name* Suffix Ziyi	M@email.con zz@email.con	_
	Sponsors Programs Products	🛔 Zhang Ziyi	Job Tide	ZZ@email.com shaista@jeff.edu	+86 3713944547 +1 215 555 5555
	Studies Organizations	📄 🚔 Kelly Hibbit	Email Address* Status* Active O This field is required	kellyh@email.con Jordan@email.con	
	Contacts User Management	Prof John Pollard	Phone Numbers	j-pollard@neuro.com Fred.Malcom@email.con	
	Activities Library Activity Plan Templates Milestone Templates	Dr. Lucy Vieira	● Add Primary ▼ ■+1 × 302-123-4568 Ext 章	lucy@vieira.com	
		Ligo Tognazzi	Phone number is invalid for the selected country	donna@email.con Ugo@email.con	
		James Martin Arbert Glockner	Complete all fields and delete unnecessary phone #(s) Include Address	James®email.con RGW@email.con	
		Rod Lockner Anny Hunter	Address Address Type* Please review these fields:	RG@email.con MLG@email.con	
		Anita Rodriguez	Email Address V Phone Numbers Phone Number 1 Address Type	Anita@email.con W@email.con	+1 212 339 1802 +1 212 339 0005
		Linda Jackson	Search Photos Ph	Linda@email.con	+1 212 335 0200 x12
•		Chris Smith	Cancel Create and Add Another Create	Orm@email.con chris@smith.edu	+1 301 456 7890
T		Chris Malcom Smith		abc@ge.go	4 Previous 1 of 5 Next ►

- 8. Finally, before clicking **Create**, verify that all the fields are entered correctly in the Create Contact window.
- 9. (Optional) Click **Create** or **Create and Add Another** depending on whether you intend to create another contact right away.

4.4 Editing a Contact at Domain, Site and Organization Levels

• The user must have been assigned the necessary permissions by the Company Administrator.

4.5 Editing a Contact

- 1. Click on the check box before the contact's name.
 - a. A quick view panel will display on the right side of the screen
- 2. Click on the **Edit** button (pencil icon) and make any necessary changes to the contact information.
- 3. Click on the **Save** button at the bottom of the quick view panel.

TI CTMS USER GUIDE v1.2

	A Contacts						Search Q AA -
	«	Contacts					
	F	🚯 Add 🥒 Edit 🔹 Belete					Q, Search
	(2)	110 Contacts 1 Selected					Zhang Ziyi
		Name	Status	Job Title	Email	Phone	(Browse)
	TrialInteractive	📄 👗 Jae Lea	ACTIVE		Jae@email.con		09 Sep 2021
		👗 Eun He Lea	ACTIVE		M@email.con		
	Deshboard	🔷 👗 Zhang Ziyi	ACTIVE		zz@email.con		General Information
	Sponsors Programs	🗹 🔮 Zhang Ziyi	ACTIVE	Principal Investigator	ZZ@email.com	+86 3713944547	Prefix First Name*
	Products	📄 🛔 Dr. Shaista Alam	ACTIVE	Principal Investigator	shaista@jeff.edu	+1 215 555 5555	Zhang
	👗 Studies	👗 Kelly Hibbit	ACTIVE	Account Executive	kellyh@email.con		Middle Name
	Organizations	📄 🔒 Jordan Martin	ACTIVE		Jordan@email.con		
	Contacts User Management	🛔 Prof John Pollard	ACTIVE	Principal Investigator	j-pollard@neuro.com	N	Last Name* Suffix
	Activities Library	Ered Malcom	ACTIVE		Fred.Malcom@email.con	12	
	Activity Plan Templates	🛔 Dr. Lucy Vieira	ACTIVE	Principal Investigator	lucy@vieira.com		Status Active
	Milestone Templates	🔷 Donna Baker	ACTIVE		donna@email.con		Job Title
		💄 Ugo Tognazzi	ACTIVE	CEO	Ugo@email.con		Principal Investigator
		📄 🛔 James Martin	ACTIVE		James@email.con		Preferred Languages 0 Language
		a Robert Glockner	ACTIVE		RGW@email.con		
		Rod Lockner	ACTIVE		RG@email.con		Preferred Communication Method
		💄 Mary Hunter	ACTIVE		MLG@email.con		
		Anita Rodriguez	ACTIVE		Anita@email.con	+1 212 339 1802	Time Zone Best Contact Time
		A Yvonne Martinez	ACTIVE		YV@email.con	+1 212 339 0005	
		📄 🛔 Linda Jackson	ACTIVE		Linda@email.con	+1 212 335 0200 x12	Contact Information
		a Orm Wensin	ACTIVE		Orm@email.con		
		Chris Smith	ACTIVE		chris@smith.edu	+1 301 456 7890	
۰		Chris Malcom Smith	ACTIVE	Site Coordinator	abc@ge.go		
T		·····	_	· •		Previous 1 of 5 Next	Cancel Save Save & Next

- 4. Make sure to check the all the fields and click on the **Save** Button for the changes to apply.
- 5. **(Optional)** Clicking on the Contact's name will open the Contact Details page. Editing a contact may also be done on the Contact Details page.

	*	🚨 Contact Zhang Ziyi 💌		Search Q 🗛 🗸
	«	< ZZ	Zhang Ziyi Principal Investigator	ZC@email.com
			2 Edt. ★ Expand All	S Edit History
			General Information	8
	i	Contact Details		œ
		Organizations Sites	Experience Information	œ
			Additional Information	æ
٠				
T				



5 Studies

5.1 Pre-Requisites

Users creating or managing Studies in an organization should have CSM user access. Company administrators will need to assign CREATE, UPDATE, EDIT and DELETE permissions/privileges to user's accounts so that they can perform these steps.

5.2 Creating a Study

- 1. Click on the **Studies** link in the Navigation menu at the left side of the screen.
 - a. This opens the "Studies" window and study list is displayed.
- 2. Click on the Add button at the top-left of the screen.
 - a. The "Create Study" window will open.

	*	Studies				a 🗛 -
	*	TrialInteractive	Studies Add Create Study Create Study Sponsor* Protocol Number* Study Name	Press F11 Therapeutic Are] to exit full scree	_
		Deshboard Sponsors Programs Products Studies Organizations Contacts	INTEGRITY, JV, 2 Derm 001 Protocol Title* M Parch Peds AciMedoo1 Role test 2 Types 0 Types Sects 92021 Sects 92021 Mul, Study Owner admin admin Diagnova Status & Status Date* Planned Owner admin admin Status Date* Planned Program Primary Product*	Pain and Anesthesi	25 0 0 0 0 0 58 0 0 1 1 5 0	400 0 0 0 0 0 0 220 0 0 0 5 5 50 0
≡ * ℃			AR-Gastro080-	Dermatology Anti-Infective	58 0 50 • Previous (250 0 520 1 of 2 Next ►

- Here, we need to enter the mandatory metadata to create a study i.e., Sponsor, Protocol Number, Protocol Title, Status, Status Date, Primary Product, Phase, Design and Blinded as indicated by asterisk (*) symbol next to the field title. Enter any additional information, as necessary.
- 4. This is also where you will indicate whether or not this is a blinded trial. You can do this directly from the Study Details page after the study has been created but this is your first chance to indicate that this study will have a blinded component.



- 5. If any of the required fields are missing, an error will appear when we click on the **Create** button, displaying the fields which need to be filled to create a study successfully.
- 6. Finally, before clicking **Create**, verify all the fields are entered correctly in the Create Study window.
 - a. The Create Study window closes, and the study record is displayed in the list.

5.3 Blinded Studies

Studies that have been indicated as blinded will have the ability to display appropriate information only to specifically indicated personnel.

5.3.1 Adding Unblinded Personnel to a Blinded Study

Unblinded personnel can only be added to a study by an unblinded study manager. In order to safeguard this information, the only way to add an unblinded study manager to a study is to contact the Trial Interactive Service Desk. Service Desk personnel will verify the intent and authenticity of the request prior to proceeding. The unblinded study manager is able to add unblinded members to the study team using the steps outlined in the related section of the User Guide.

5.4 Editing a Study

- 1. Click on the **Studies** link in the Navigation menu at the left side of the screen.
 - a. This opens the "Studies" window, and the study list is displayed.
- 2. Click on the check box next to the name of the study and click on the **Edit** button at the top-left of the screen.
 - a. The "Study Details" window is displayed.

TI CTMS USER GUIDE v1.2

	*	Studies								2	iearch	Q (M) -
	«		Stu	dies								
		F	A	dd 🥒 Edit						Press F1	1 to exit full scree	en 🔻 Filters
			35 Studies 1 Selected									
		TrialInteractive		Name	Protocol Number	Status	Sponsor	Program	Phase	Therapeutic Are	# Planned Trial	# Planned Subje
				INTEGRITY_IV	INT-IV-001	Planned	Dermeron	Integ_IV	IV	Pain and Anesthesi	25	400
	63	Dashboard		Derm-001	Der992021	Protocol Synopsis Ava	Dermeron		0-00		0	0
		Sponsors		MI Patch Peds	MI001-136	Planned	Medical Immu		1-11		0	0
		Programs							I-II Iç			
	<u>ش</u> ۲	Products Studies		Role test 2	817922021	Planned	May & May Ph		1,5"		0	0
		Organizations		May Study Tes	813922021	Planned	May & May Ph		1		0	0
		Contacts		Scotts 92021	1229912021	Planned	Scott Works		ш	Endocrine	58	220
		User Management Activities Library		Anuj	2238312021	Submitted to Reg Aut	Medical Immu		н		0	0
		Activities Library Activity Plan Templates		W4U-Study	2148272020-W4U	Planned	Working 4U		1		0	0
	9	Milestone Templates		Diagnova	00123	Planned	A+ Drugs		1		1	5
				Test1	001	Submitted to Reg Aut	A+ Drugs		0		5	50
				Downton Now	B215302	Enrolling	A+ Drugs	abc	н	Unknown	0	0
٠												
T												_
6											Previous	1 of 3

- 3. Make any necessary changes to the Study information.
- 4. Click the **Save** button for the changes to apply.

	#	Study INTEGRITY_IV_001	Study Details		Search Q A
	«		INTEGRITY_IV_001 ∰ Dermeron≵ Integ IV		Planned
			Save Collapse All		D Edit History
	INTE	GRITY_IV_001	Sponsor		1
			Virtual Study 💽 3		
	i Stu				
		idy Details shboard	Protocol Information		
		lestones			
	-	untries	Protocol Title* Protocol title	Phase*	
	Site	es bjects	i oteo de		
		ganizations		Types 1 Types New indication ×	
		ntacts	Protocol Summary		
	🛉 Tea	am			
	C Act	tivities		Mechanisms 0 Mechanisms	
	🛄 Act	tivity Plans		Select	
			Therapeutic Areas 1 Therapeutic Areas		
=			Pain and Anesthesia X X	Objectives 0 Objectives	
				Select	
٠					
			Indications 0 Indications Select		
To				Designs 1 Designs* Open-Label ×	
				· · · · · · · · · · · · · · · · · · ·	

5.5 Entering Study Settings

- 1. Click on the **Studies** link in the Navigation menu at the left side of the screen.
 - a. This opens the "Studies" window and study list is displayed.
- 2. Click on the name of the study in the list.
 - a. The dashboard for the study is displayed.
- 3. Click on the Study Details in the Navigation menu at the left side of the screen.
 - a. The "Study Details" window is displayed.

	*		Dashboard		
	*		KingDerm1 ≣ King Research		Planned
		KingDerm1	Study Enrollment Status All v Year All v Country All v Site All v	± Export ∼	
	i đìo V	Study Details Dashboard Milestones			
		Countries Sites Subjects Organizations	l>		
	₩ *	Contacts Team Activities	NO DATA FOUND		
		Activity Plans			
≣ ≎					
Ť					



- 4. Click **Settings** in the top-right corner of the **study details** window.
 - a. This opens Study Settings General window.

	★ study KingDerm1 ▼	Study Details			Search	Q (AA -
	× д	KingDerm1				Planned
		🖋 Edit 🛛 👻 Expand All			à	D Edit History
	KingDerm1					Settings
		General Information				•
	i Study Details					
	Dashboard	Protocol Information				æ
	Milestones Countries					
	Sites	Project Management				æ
	L Subjects					
	Organizations	Subject and Recruitmer	nt			•
	📽 Contacts	# Planned Trial Sites		# Planned Subjects Entered Trial	Enrolled 🚱	
	Activities	100		1,000		
	Activity Plans	First Site Enrolled	Last Site Closed	# Planned Subjects Entered Treatment	Completed	
				0		
				# Planned Subjects Completed Treatment	Screened	
≣					Randomized	
٠					Screen Failed	
T						
6					UAT - Actual	

5. Click Edit from the study settings window at the top-left of the screen.

This document is proprietary and is protected by U.S. and international copyright laws and trade secret laws. Copyright © 2021 TransPerfect International, Inc. (TransPerfect). All rights reserved. No part of this document may be reproduced, copied, adapted, modified, distributed, transferred, translated, disclosed, displayed or otherwise used by anyone in any form or by any means without the express written authorization of TransPerfect Senior Management and/or Product Management. Other names may be trademarks of their respective owners.

	★ < ··· A Study KingDerm1 ▼ S	General			Search Q. AA -
	×	KingDerm1			Planned
	(– (✔ Edit			ී Edit History
	KingDerm1	General Settings			8
	🔅 General	Subject Tracking			
	Regions Milestone Templates	Monitoring Information		đ	•
		SVR Submission Days	SVR Approval Days		
		Site Visit Frequency			
		0 Types			
		Visit Type		Frequency	
			No record	ls available	
=					
٠		Reviewers			=
C		0 Reviewers	Feasil	8boog	

- 6. Make any necessary changes in the Study Settings General window.
- 7. Click on **Save** at the top-left of the window.

T R I A L INTERACTIVE

	★ Study KingDerm1 ▼	Study Settings General	Search Q AA •
	» д	KingDerm1	Planned
		Save Cancel A Collapse All	ී Edit History
	KingDerm1	General Settings	•
	🔅 General		
	Regions Milestone Templates	Monitoring	=
		SVR Submission Days SVR Approval Days SVR Visit Frequency	
		🕞 Add 🥒 Edit 🁔 Delete	Q, Search
		0 Types	
		Visit Type Frequency	
		No records available	
=			
٠			
C		Reviewers	8



Version 1.0 Page 34 of 130

Note: Turning off Subject Tracking will prevent the creation of subject records. Actual subject enrollment statistics are still rolled-up from the site level.

5.6 Defining Study specific Regions

- 1. Click on the **Studies** in the Navigation Menu at the left side of the screen.
 - a. This opens the "Studies" window.
- 2. Click on the name of the study for which you want to define regions.
 - a. This opens the dashboard for the study.
- 3. Click on the **Study Details** in the Navigation menu at the left side of the screen.
- 4. Click on the **Settings** button in the top-right corner of the screen.
 - a. This opens the **Study Settings** window.
- Click on **Regions** in the Navigation menu at the left side of the screen.
 a. The "Regions Window" is displayed.
- 6. Click on the **Add** button at the top-left of the screen.
 - a. This opens the "Create Region" Window.
- 7. Here we need to enter the mandatory metadata to create a Region i.e., **Region Name, Countries** as indicated by an asterisk (*) symbol next to the field title. Enter any additional information, as necessary.
- 8. Click **Create** or **Create and Add Another** depending on whether you intend to create another Region right away.

	Study	Study Settings	Regions	Search Q	AA -
	<u>«</u>	Regions	te 🥒 Edit		Filters
	INTEGRITY_IV_001	0 Regions Region	Create Region 🗖 🗙	Cities	
	General Regions Milestone Templates	1	Region Name*		
			State/Province		
			Cancel Create and Add Another Create		
≣					
•					
C					



Note: To enter the State/Province and Cities values you must select only a **single country** for your region definition.

5.7 Editing Study Regions

- 1. Navigate to the Regions area for the study you wish to edit.
 - a. The necessary steps are found here.
- 2. Click on the region name from the list you want to Edit.
 - a. This opens "Region Details" window.
- 3. Click on the **Edit** button in the-top-left corner.

	▲ ▲ study INTEGRITY_IV_001 ▼	Study Settings		
		A+ ✓ Edit ★ Collapse All		
	A+	Region Information		•
		Region Name*	Study INTEGRITY_IV_001	0
	i Region Details	Country 1 Country* Q United States	City 0 City	
		United States		
		State/Province 0 State/Province		
		à		
≡				
٠				
C				

- 4. Make any necessary changes in the **Region Details** window.
- 5. Click on **Save** button in the top-left for the changes to apply.

TI CTMS USER GUIDE v1.2

	A ≤ *** A Study INTEGRITY_IV_001 ▼	Study Settings		Search	<u> </u>
		A+ Save D Cancel A Collapse All			
	A+	Region Information	Study INTEGRITY_IV_001		•
	i Region Details	Country 1 Country*	City 0 City		
		State/Province 0 State/Province			
٠					
C					

5.8 Defining and Editing Countries Within a Study.

- Click on **Studies** in the Navigation Menu at the left side of the screen.
 a. This opens the "Studies" window.
- Click on the name of the study in which you want to define countries.
 a. This opens the dashboard for the study.
- 3. Click on **Countries** link in the Navigation menu at the left side of the screen.
 - a. This opens the "Countries" window, and countries list is displayed.
- 4. Click **Add** in the top-left of the screen.
 - a. This opens Create Study-Country window.
- Here we need to enter the mandatory metadata to create a Region i.e., Country, Owner, Status, Status Date as indicated by an asterisk (*) symbol next to the field title. Enter any additional information, as necessary.
- Click the Create button, the country is created, and the "Create Study-Country" window is closed.

	A Study INTEGRITY_IV_001 ▼	Countries	Search Q AA -
	×π	Countries	
	INTEGRITY_IV_001	Add ✓ Edkl Create Study-Country □ × 4 Countries 1 Select Study Name Regions Country Study Name INTEGRITY_IV_001	Q. Search T Filters
	Study Details Dashboard Countries Sites Sites Cognitations Cognitations Contacts Team Activities	United State Country* Country Code Country Code Country* C	
:::: *	Activity Plans	Cancel Create	b.

- 7. To edit the country, click on the check box before the name of the country you want to edit.
- 8. Click **Edit** in the top-left of the screen.
 - a. A quick view panel will display on the right side of the screen.
- 9. Make any necessary changes in the quick view panel.
- 10. Click Save.

T R I A L INTERACTIVE

		Countries						Search Q AA -
	« п	Countries						
		🕒 Add 🧪 Edit	🗊 Delete					Q Search Tilters
	INTEGRITY_IV_001	4 Countries 1 Selecte	d					Germany
		Country Germany	Country Code	Status	Owner	Regions	Notes	Active
	i Study Details	O United States		UAT Country				General Information
	Dashboard	🕘 🛛 Q Canada	сл	UAT Country				Country Country Code
	Milestones Countries	🛛 Brazil	BR	UAT Country				Germany DE
	Sites Subjects							Study INTEGRITY_IV_001
	Organizations Contacts							Notes
	🛉 Team							
	Activities							
								Country Management
=								Status Status Date Active 15 Sep 2021
								Change Status
٠								Cancel Save & Next
C								<pre>Cancer Save & Next > </pre>

5.9 Associating Organizations to a Study

T R I A L INTERACTIVE

- 1. Click on the **Studies** link in the Navigation menu at the left side of the screen.
 - a. This opens the "Studies" window.
- Locate the study to which you want to associate an organization and click on it.
 a. This opens the dashboard for that study.
- 3. Click on the **Organization** link in the Navigation menu at the left side of the screen.
 - a. This opens the "Organization" window, organizations associated to the study are displayed.
- 4. Click on the Add button at the top-left of the screen.
 - a. This opens the "Add Organization" window.

	#	≤ ••• ▲ Study KingDerm1 ▼	Organizations	Add Organization	×		Search Q AA -
	*		Organization	Q Search for the Organizations General Information Name*			Q Search Titters
		KingDerm1	Name King Trucking an	Number*		Subtype	Primary Contact
	i ∰ ♀	Study Details Dashboard Milestones Countries		Type* Subtype			
	•	Sites Subjects Organizations		Status* Active V Primary Contact			
≣ ≎	÷	Team Activities Activity Plans		Phone Numbers O Add	<u> </u>		
C				Cancel Select and Add Another Create			

- 5. If you need to create a new organization, follow these steps showing how to create an <u>Organization</u>.
- 6. If the organization has already been created, use the search area to locate and select the organization.
- 7. Click **Add** or **Add and Add Another** depending upon whether you need to associate another organization to this study.

5.10 Defining Study Partners

- 1. Click on the **Studies** link in the Navigation menu at the left side of the screen.
 - a. This opens the "Studies" window and study list is displayed.
- 2. Click on the name of the study to which you want to add partner information.
 - a. The dashboard for the study is displayed.
- 3. Click on the Study Details in the Navigation menu at the left side of the screen.

This document is proprietary and is protected by U.S. and international copyright laws and trade secret laws. Copyright © 2021 TransPerfect International, Inc. (TransPerfect). All rights reserved. No part of this document may be reproduced, copied, adapted, modified, distributed, transferred, translated, disclosed, displayed or otherwise used by anyone in any form or by any means without the express written authorization of TransPerfect Senior Management and/or Product Management. Other names may be trademarks of their respective owners.



- a. The "Study Details" window is displayed.
- 4. Click on the [+] sign next to the Partner Information to expand that section.
- 5. Click on the **Edit** button in the top-left of the screen.

	★ Study KingDerm1 ▼	Study Details	Search Q A
	≪д	KingDerm1 ■ King Research	Planned
		✓ Edit V Expand All	D Edit History
	KingDerm1	General Information	0
		Protocol Information	Đ
	i Study Details		
	Dashboard Milestones	Project Management	•
	Milestones Countries		
	Sites	Subject and Recruitment	•
	🛓 Subjects	Informed Concert	
	Organizations Contacts	Informed Consent	•
	Team	Partner Information	
	Activity Plans	Monitoring Partner	
		Data Management Partner	
		8	
		Lab Handling Partner	
٠		8	
\sim			
C		Additional Information	•

- 6. Make the necessary changes in the partner information section.
- 7. Click the **Save** button in the top-left of the screen.

	★ study KingDerm1 ▼	Study Details	Search Q AA -
	« Д	KingDerm1	stanned
		Save Save Cancel V Expand All	2 Edit History
	KingDerm1	General Information	8
		Protocol Information	œ
	i Study Details		
	Dashboard	Project Management	⊞
	Milestones Countries Sites	Subject and Recruitment	
	. Subjects Organizations Contacts	Informed Consent	œ
	🛉 Team	Partner Information	-
	Activity Plans	Monitoring Partner	
		Data Management Partner	
٠		Lab Handling Partner	
C		Additional Information	

5.11 Associating Contacts to a Study

- 1. Click on the **Studies** link in the Navigation menu at the left side of the screen.
 - a. This opens the "Studies" window and study list is displayed.
- 2. Click on the name of the study to which you want to associate contacts.
 - a. The dashboard for the study is displayed.
- 3. Click on the **Contacts** link in the Navigation menu at the left side of the screen.
 - a. This opens the "Contacts" window and all the contacts for the study are listed.
- 4. Click on the **Add** button at the top-left of the screen.
 - a. This opens the Create Contact in Study window.
- Here we need to enter the mandatory metadata to create a Contact i.e., Organization, First Name, Last Name, Contact Role, Email Address, Status as indicated by an asterisk (*) symbol next to the field title. Enter any additional information, as necessary.
- 6. **(Optional)** Click on the **Add** symbol below **Phone Number** to add a contact number to that person.

Note: When creating a contact record with at least one phone number, you will need to designate one phone number as the primary number.

7. **(Optional)** Click **Include Address**, select a type for the address, and enter the address information.

Note: The Search functionality can be utilized to search for addresses.

This document is proprietary and is protected by U.S. and international copyright laws and trade secret laws. Copyright © 2021 TransPerfect International, Inc. (TransPerfect). All rights reserved. No part of this document may be reproduced, copied, adapted, modified, distributed, transferred, translated, disclosed, displayed or otherwise used by anyone in any form or by any means without the express written authorization of TransPerfect Senior Management and/or Product Management. Other names may be trademarks of their respective owners.



- 8. Finally, before clicking **Create**, verify all the fields are entered correctly in the **Create Contact in Study** window.
- 9. **(Optional)** Click **Create** or **Create and Add Another** depending on whether you intend to create another Contact right away.

Note: Contacts can only be created for organizations associated to the study.

10. When editing one of the contact records from the list, only data that is part of the contextual to study can be updated.

		iontacts			
	« д	contacts of cate contact in starty	= ×		
		Add Fdit Q Search for Contacts	0		Q Search
		0 Contacts General Information			G
	KingDerm1	Name Organization*	Phone	Start Date	End Date P
			~		
		Prefix First Name* Middle Name	-		
	1 Study Details		_		
	 Dashboard Milestones 	Last Name* Suffix		D ₂ -	
	Countries				
	🗒 Sites	Job Title Contact Role*			
	L Subjects		✓		
	Organizations	Email Address*	_		
	Team	Active			
	Activities	Start Date End Date day month year			
	Activity Plans	ay nonch year			
		Phone Numbers			
		Q Add			
≣					
٠		Cancel Create and Add Another Create			
\sim			_		
C					

5.12 Creating Sites within a Study

- Click on the **Studies** link in the Navigation menu at the left side of the screen.
 a. This opens the "Studies" window and study list is displayed.
- Click on the name of the study to which you want to add Sites.
 - a. The dashboard for the study is displayed.
- 3. Click on the **Sites** link in the Navigation menu at the left side of the screen.
 - a. This opens the "Sites" window, and all the sites are listed for the study.
- 4. Click on the **Add** button at the top-left of the screen.
 - a. This opens the **Create Site** window.

This document is proprietary and is protected by U.S. and international copyright laws and trade secret laws. Copyright © 2021 TransPerfect International, Inc. (TransPerfect). All rights reserved. No part of this document may be reproduced, copied, adapted, modified, distributed, transferred, translated, disclosed, displayed or otherwise used by anyone in any form or by any means without the express written authorization of TransPerfect Senior Management and/or Product Management. Other names may be trademarks of their respective owners.



- Here we need to enter the mandatory metadata to create a site i.e., Site Number, Principal Investigator, Site Organization, Site Location, Owner, Status and Status Date as indicated by an asterisk (*) symbol next to the field title. Enter any additional information, as necessary.
 - a. If the site is a satellite site, this is also where you would identify the parent site. Please note that the parent site will need to already be created and associated with the study before identifying a site as a satellite site.

Note: The **Site Number** field is limited to 5 characters. Satellite sites can either have a unique site number or they can use the same number as the parent site.

		Sites	Search Q 🗛 🗸
	۰ ح	Sites Create Site	
	KingDerm1	All Sites Active General Information Add Carlot Add 2 Sites Study ⁴ This is a satellite site	Q Search T Filters
	 Study Details Dashboard Milestones Countries Stop Subjects Organizations Contacts Team Activities Activity Plans 	Name Region Bash 961 Site Number* Bash 961 Site Name Site Organization* Site Location* Owner* admin admin	Completed Milestone
≡ *		Status Date* New O Status Date* 18 Sep 2021	

- 6. Finally, before clicking **Create**, verify all the fields are entered correctly in the **Create Site** window.
- 7. **(Optional)** Click **Create** or **Create and Add Another** depending on whether you intend to create another Site right away.

5.13 Reviewing Subjects Within a Study

This document is proprietary and is protected by U.S. and international copyright laws and trade secret laws. Copyright © 2021 TransPerfect International, Inc. (TransPerfect). All rights reserved. No part of this document may be reproduced, copied, adapted, modified, distributed, transferred, translated, disclosed, displayed or otherwise used by anyone in any form or by any means without the express written authorization of TransPerfect Senior Management and/or Product Management. Other names may be trademarks of their respective owners.



Note: Subjects is only available if the study is tracking subjects within CTMS. This list will be populated with the current list of subjects for the study.

- 1. Click on the Studies link in the Navigation menu at the left side of the screen.
 - a. This opens the "Studies" window and study list is displayed.
- 2. Click on the name of the study whose subjects you wish to review.
 - a. The dashboard for the study is displayed.
- 3. Click on the Subjects link in the Navigation menu at the left side of the screen.
 - a. This displays all the subjects for the study.

	*	≪ •••	Subjects				Search	Q 📣 -
	«		Subjects					
			🖉 Edit		ţ.		Q Search	T Filters
		KingDerm1	0 Subjects					G
		-	Subject ID	Status	Screening Number	Subject Initials	Site	OPEN
					No records available			
	i 1930	Study Details Dashboard						
	0	Milestones						
	Q	Countries						
	Ê	Sites						
	Ŀ	Subjects						
		Organizations						
	*	Contacts Team						
		Activities						
		Activity Plans						
≡								
۰								
T								

5.14 Study Sites Pre-Requisites

The user who is responsible for creating or managing sites in any study should have **CRA** user access. Company administrators will need to assign CREATE, UPDATE, EDIT and DELETE permissions/privileges to users' accounts so that they can perform these steps.

5.15 Editing a Site in a Study

1. Click on the Studies link in the Navigation menu at the left side of the screen.



- 2. Navigate to the study you want to access.
- 3. Click on **Sites** in the Navigation menu at the left side of the screen.
 - a. This opens the "Study Site" window and study site list is displayed.
- 4. Click on the name of the site you want to edit.
 - a. This opens the dashboard window for the site.
- 5. Click on Site Details in the Navigation menu at the left side of the screen.
 - a. This opens the "Site Details" window for the site.
- 6. Click on the **Edit** button at the top-left of the screen.

	*	≪ •••• Ā Study Derm-001 ▼	Site Baker - 740 ▼ Site Details				Search	
	«		Baker - 740 ■ Bake OBGYN& Donna Baker ✓ Edit → Expand All					New D Edit History
		Baker - 740 Donna Baker Bake OBGYN	Site Informatio	n		Site Location		•
			Derm-001		6	3645 Las Vegas Boulevard South		
	i	Site Details	Schilder		•	Sous Las regas Boaleval à Souar		
	•	Dashboard	Site Number	Principal Investigator		Regions		
	9	Milestones	740	Donna Baker	Change			
		Site Visits	Site Name					
	L	Subjects	Baker - 740					
		Organizations	Site Organization			Notes		
	쓭	Contacts	Bake OBGYN					
		Team						
		Activities						
		Activity Plans						
۵								
¥								
E			Site Manageme	ent				

- 7. Make the required changes in the site details window.
- 8. Click on the Save button at the top-left of the screen for the changes to apply.

This document is proprietary and is protected by U.S. and international copyright laws and trade secret laws. Copyright © 2021 TransPerfect International, Inc. (TransPerfect). All rights reserved. No part of this document may be reproduced, copied, adapted, modified, distributed, transferred, translated, disclosed, displayed or otherwise used by anyone in any form or by any means without the express written authorization of TransPerfect Senior Management and/or Product Management. Other names may be trademarks of their respective owners.

	ñ	≪ ••• Ā Study Derm-001 ▼	🖹 Site Baker - 740 👻 Site Details	Search	
	«		Baker - 740 ■ Bake OBGYN& Donna Baker © Save ⊃ Cancel ♥ Expand All		New D Edit History
		Baker - 740 Donna Baker Bake OBGYN	Site Information		•
	i 20 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Site Details Dashboard Milestones Site Visits Subjects Organizations Contacts Team Activities	Study Site Location Derm-001 Image: Stell testice This is Satellite Site Principal Investigator* 740 Donna Baker Site Name* Select Baker - 740 Image: Stellite Site Site Organization Site Organization Image: Select Image: Site Organization Image: Select		
: * E		Activity Plans	Site Management		œ

5.16 Tracking Informed Consents (ICFs) for a Site

- 1. Navigate to the Site Details area for the related site.
 - a. The necessary steps are found <u>here</u>.
- 2. Click on the [+] sign next to the Informed Consent to expand that section.

	ñ	≪ ***	🖹 Ste Baker - 740 👻	Search	Q 🗛 -
	«		Baker - 740 II Bake OBGYN& Donna Baker	2	New
			✔ Edit ¥ Expand All		ී Edit History
		Baker - 740 Donna Baker Bake OBGYN	Site Information		æ
			Site Management		æ
		Ste Details Dashboard Milestones Ste Visits Subjects Organizations Contacts Team Activities Activity Plans	Informed Consent Site Addresses Subject and Recruitment		6
≡ ≎					
C					

- 3. Click on the **Edit** button in the top-left of the screen.
- 4. Click on the **Add** button in the informed Consent section.

		Ste Baker - 740 ▼ Site Details	Search Q AA -
	«	Baker - 740 ■ Bake OBGYN& Donna Baker ✓ Edit v Expand All	S Edit History
	Baker - 740 Donna Baker Bake OBGYN	Site Information	
	i Site Details	Site Management	
	Dashboard Milestones Site Visits		Q Search
	 Subjects Organizations Contacts 	0 Informed Consents	
	🛉 Team	Name Effective Date	
*		Site Addresses	
C		Subject and Recruitment	Π

5. Enter site specific Name and Effective Date.

This document is proprietary and is protected by U.S. and international copyright laws and trade secret laws. Copyright © 2021 TransPerfect International, Inc. (TransPerfect). All rights reserved. No part of this document may be reproduced, copied, adapted, modified, distributed, transferred, translated, disclosed, displayed or otherwise used by anyone in any form or by any means without the express written authorization of TransPerfect Senior Management and/or Product Management. Other names may be trademarks of their respective owners.

	(/ aaa	Baker - 740 ▼	Search Q AA -
	« H	Baker - 740 B Bake OBGYN& Donna Baker	Rev
		✔ Edit	ී Edit History
	Baker - 740 Donna Baker Bake OBGYN	Site Information	œ
		Site Management	
	i Site Details		
	 Dashboard Milestones 	Informed Consent	
	Site Visits		
	Subjects	Save Cancel	Q Search
	Organizations		
	Market Contacts	0 Informed Consents	
	🛉 Team	Name Offertive Date	
	Activities	day month year	#
	Activity Plans	Mark	
		Create "Mark" available	
		NO DATA	
٠			
		Site Addresses	⊞
C		Subject and Recruitment	æ

- 6. Click Create.
- Click on the Save button in the informed consent section to save the record.
 a. This creates site level ICF for the site.

5.17 Tracking Site Addresses

- Navigate to the Site Details area for the related site

 The necessary steps are found here.
- 2. Click [+] next to the site addresses to expand that section.
- 3. Site location within the site addresses section is displayed as primary address.
- 4. Site Location is listed as a primary address for the site.
- 5. Click on the Add button under Site Addresses section.
 - a. This opens the Add Address window.
- 6. Here we need to enter the mandatory metadata to create an Address i.e., Address Type, Organization, Address as indicated by an asterisk (*) symbol next to the field title.
- 7. Click on the **Save** button.

Note: Only addresses associated to the selected site organization are available for selection.

		≪ ===	© Ste Baker-740 ▼ Ste Details	Search Q A
	•		Baker - 740 Bake digtNA Denna Baker	Firm
			✓ Edit V Expand All	ා Edit History
		Baker - 740 Donna Baker Bake OBGYN	Site Information	Θ
	i	Site Details	Site Management	œ
	0	Dashboard Milestones Site Visits	Informed Consent Add Address	•
	問 留 令 ()	Subjects Organizations Contacts Team Activities Activities	Site Addresses Adversityet* Visit is besit of selection orgenization* Primary orgenization* 3645 Las Vegas, Boulevard South Adversityet* B9109 Careel Selection	G Search
			United States Subject and Recruitment	8
٠				
T				

5.18 Associating an Organization to a site

- 1. Navigate to the Site to which you wish to associate an organization.
- 2. Click on the **Organization** link in the Navigation menu at the left side of the screen.
 - a. This opens the "Organization" window.
- 3. Click on **Add** button at the top-left of the screen.
 - a. This opens "Add organization" window.

		Organizations			Search Q 🗛 🗸
	• Joerm-001	Organizations C Ada C C C C C C C C C C C C C C C C C C C	a Add Organization	X Subtype	C. Search T Plans
	 Surdy Dearls Dathsand Micromes Countrs Seas Contexts Contexts Contexts Annuity Plans 		Q. Search for the Organization General Information Function Fu		
•					

- 4. Here we need to fill the required metadata to create an organization with an address.
- 5. Click on the **Create** button.

5.19 Change of Principal Investigator (PI)

- 1. Navigate to the Site Details area for the related site.
 - a. The necessary steps are found here.
- 2. Click on the [+] sign next to the Site Information to expand that section.
- 3. Click on the **Change** button in the site information section.



	*		Site Site Details			Search Q AA -
	*		Baker - 740			New
			✔ Edit			D Edit History
		Baker - 740 Donna Baker	Site Information			
		Bake OBGYN	Study		Site Location	
	1	Site Details	Derm-001	0	3645 Las Vegas Boulevard South	
		Dashboard	Site Number Principal Ir	nvestigator	Regions	
	0	Milestones	740 Donna B			
		Site Visits	Site Name			
	1	Subjects	Baker - 740			
		Organizations	Site Organization		Notes	
	쇖	Contacts	Bake OBGYN			
	+	Team				
	Ċ	Activities				
		Activity Plans				
			Site Management			۲
			Informed Consent			⊞
			Site Addresses			Ð
			Subject and Recruitment			⊞
٠						
C						

- 4. Confirmation window is popped up, select **Yes** in the confirmation window.
 - a. This opens "Change Principal Investigator" window.

Note: Use the search box to find the contact.

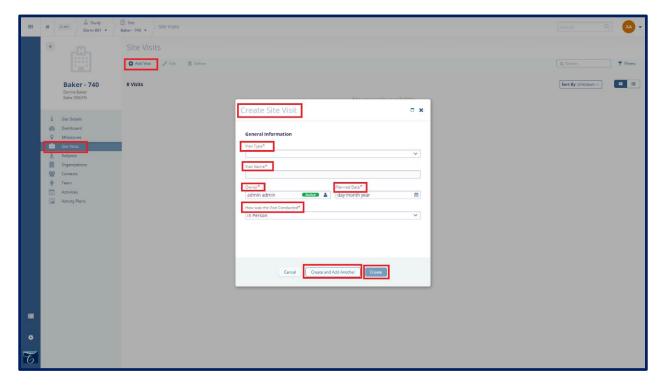
5. Click on the **Save** button.

	*		🖹 Site Bøker - 740 👻 Site Details						Search Q 🗛 🗸
	×		Baker - 740 Bake OBGYN& Donna Baker						
			✓ Edit V Expand All	Char	- Daile also di la constitu		- ×		D Edit History
		Baker - 740 Donna Baker Bake OBGYN	Site Information		ge Principal Investig	ator	0 ×		-
			Study				U		
		Site Details	Derm-001	Develop	Information First Name*	Middle Name		alevard South	
		Dashboard		Incipal Ir	First Name	MIGDIE Name			
		Milestones Site Visits	Site Name						
	1	Subjects	Baker - 740	Last Name	r		Suffix		
		Organizations	Site Organization	Job Title		Contact Role*			
	상 *	Contacts	Bake OBGYN	Joo noe		Principal Investigator			
		Activities		Email Addr	***	Status*			
		Activity Plans				Active			
				Start Date		End Date			
			Let us	day mon	th year 📫	day month year	#		
			Site Management						æ
			Informed Consent	Phone N • Add	umbers				œ
			Site Addresses						
			Subject and Recruitment	t	Cancel	Save			
i=				_			_		
۰									
T									



5.20 Creating Site Visits

- 1. Navigate to the site for which you wish to create a site visit.
- Click on Site Visits in the Navigation menu at the left side of the screen.
 a. This opens "Site Visits" window.
- Click on the Add Visits button at the top-left of the screen.
 a. This opens "Create Site Visit" window.
- Here we need to enter the mandatory metadata to create a Site Visit i.e., Visit Type, Visit Name, Owner, Planned Date, how was the visit Conducted as indicated by an asterisk (*) symbol next to the field title.
- 5. If any of the required fields are missing, an error will appear when we click on the **Create** button, displaying the fields which need to be filled to create a Site Visit successfully.
- 6. Finally, before clicking **Create**, verify all the fields are entered correctly in the create Site Visit window.
 - a. Create Site Visit window closes, and site visit record is created and displayed in the list.
- 7. (Optional) Click **Create** or **Create and Add Another** depending on whether you intend to create another Site Visit right away.





5.21 Updating a Site visit

T R I A L INTERACTIVE

- 1. Navigate to the site whose visit you need to update.
- Click on the Site Visits in the Navigation menu at the left side of the screen.
 a. This opens "Site Visits" window.
- 3. Navigate to the Site Visit record you want to update and click on the name.
 - a. This opens "Visit General Information" window.
- 4. Make the required changes in this window for the site visit.
- 5. Click on the **Save** button which is at the bottom of the screen.

	Study Derm-001 •	i Site and Site Visit Baker - 740 ▼ Last Visit ▼ Visit General Information				Search Q 🗛 🗸
		Last Visit				Florend
		# Collapse All				D Edit History
	Last Visit	Visit Information				
		Visit Type*	Visit Status [®]			
		Close out V	Planned	0 ~	Duration Hours Days	
	Visit General Information Visit Attendees	Visit Name*			General Comment	
	Locations	Last Visit				
	Visit Checklist	Owner*	Visit Planned Date*	e (
	0	6				
	Activities	Visit Start Date day month year	Visit End Date	m)		
	Subjects Enrollment Summary	How Was The Visit Conducted*	Visit Checklist Tem			
	Visit Report	In Person 🗸		~]		
	O Confirmation Letter					
	Follow-Up Letter	Visit Report				
				Report Status	Reviewer	
			-			
			19			
		2				
		Gen	erate Draft Report			
٠						
T		Previous Step		 Add Activity Discard Ch 	Anges Save Save and Next	Next Step >

5.22 Tracking Subjects

- 1. Navigate to the site whose subjects you wish to track.
- 2. Click on **Subjects** in the Navigation menu at the left side of the screen.
 - a. This opens the "Subjects" window.
- 3. Click on the **Add** button at the top-left of the screen.
 - a. This opens Create Subject window.
- Here we need to enter the mandatory metadata to create a Subject i.e., Subject ID, Status, Status Date as indicated by an asterisk (*) symbol next to the field title. Enter any additional information, as necessary.

This document is proprietary and is protected by U.S. and international copyright laws and trade secret laws. Copyright © 2021 TransPerfect International, Inc. (TransPerfect). All rights reserved. No part of this document may be reproduced, copied, adapted, modified, distributed, transferred, translated, disclosed, displayed or otherwise used by anyone in any form or by any means without the express written authorization of TransPerfect Senior Management and/or Product Management. Other names may be trademarks of their respective owners.



- 5. If any of the required fields are missing, an error will appear when we click on the **Create** button, displaying the fields which need to be filled to create a subject successfully.
- 6. Finally, before clicking **Create**, verify all the fields are entered correctly in the create subject window.
 - a. Create Subject window closes, subject record is created and displayed in the list.
- 7. (Optional) Click **Create** or **Create and Add Another** depending on whether you intend to create another subject right away.

Note: Subjects will not be displayed for navigation when Subject Tracking is turned off within Study > Settings for the study.

	*		© Sae Baok-961 ≠ Subjects	<u> </u>
	×		Subjects O Add # fate O Subjects	T Filters
		Bash-961 Betty Bash Daily Clinic - Atlanta	Subject ID Status Screening Number Subject Initial	OPEN
	620	Site Details Deshboard Milestones	Create Subject • ×	
	=	Site Visits Subjects	Study* KingDerm1	
		Organizations Contacts	5xx* B35h-961	
	•	Team	Subject (D*	
		Activity Plans	Steams* Seam Ders* successed O V (daymonth year	
			Date of Birth Subject Initials (day month year	
			Cancel Create and Add Another Create	
=				
T				

5.23 Editing a Subject

- 1. Navigate to the site whose subject requires editing.
- 2. Click on the **Subjects** in the Navigation menu at the left side of the screen.
 - a. This opens the "Subjects" window.
- 3. Click on the checkbox before the Subject name.
 - a. A quick view panel will display on the right side of the screen.
- 4. Now, click on the Edit button (pencil icon) in the top-right of the screen.a. This opens the "Subject Details" window.
- 5. Make any necessary changes to the subject information.
- 6. Click on the **Save** button at the top-left of the screen.

This document is proprietary and is protected by U.S. and international copyright laws and trade secret laws. Copyright © 2021 TransPerfect International, Inc. (TransPerfect). All rights reserved. No part of this document may be reproduced, copied, adapted, modified, distributed, transferred, translated, disclosed, displayed or otherwise used by anyone in any form or by any means without the express written authorization of TransPerfect Senior Management and/or Product Management. Other names may be trademarks of their respective owners.

TI CTMS USER GUIDE v1.2

		Site § Subject Bash-961 ▼ 123456 ▼ Subject Details			Search Q. A
	•	123456 @ Bash-961			Streamed
		Save Save All			D Edit History
	123456 Bash-961	Subject Information			•
		Subject ID*	Subject Initials	Screening Number	
	i Subject Details	123456			
	Subject Visits	Date of Birth	Site	Informed Consent Name Signature Date	
		day month year 📫	Bash-961		Add
		Enrollment ID	Randomization ID	C Informed Consent - History	
		Subject History Current Status Madi Datain Status Server Current Current Status	Date 12 Sep 2021	Screening Palure Reason (0) Early Termination Reason (0)	
		Summary Information			
		Notes		Subject Outcome	
٠					
T					

5.24 Tracking Subjects Visits

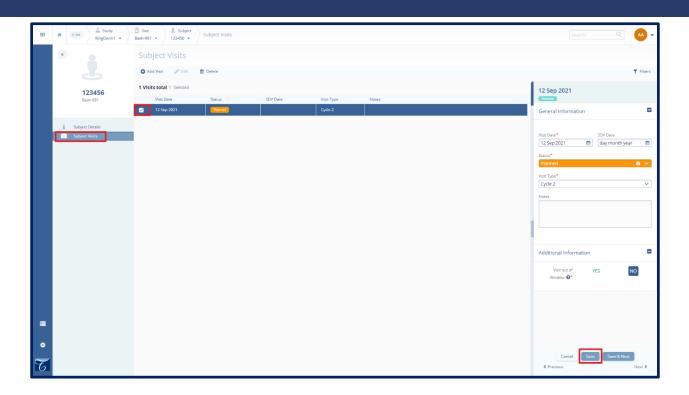
- 1. Navigate to the site in question.
- 2. Click on the **Subjects** in the Navigation menu at the left side of the screen.
 - a. This opens the "Subjects" window.
- 3. Navigate to the subject name you want to access and click on it.
- 4. Click on the **Subjects Visits** in the Navigation menu at the left side of the screen.
 - a. This opens "Subject Visits" window.
- 5. Click on the Add Visit button in the top-left of the screen.
 - a. This opens Create Subject Visit window.
- Here we need to enter the mandatory metadata to create a subject visit i.e., Visit Status, Visit Type, Visit Date as indicated by an asterisk (*) symbol next to the field title. Enter any additional information, as necessary.
- 7. If any of the required fields are missing, an error will appear when we click on the **Create** button, displaying the fields which need to be filled to create a subject successfully.
- 8. Finally, before clicking **Create**, verify all the fields are entered correctly in the create subject visit window.
 - a. Create Subject Visit window closes, subject visit record is created and displayed in the list.
- 9. **(Optional)** Click **Create** or **Create and Add Another** depending on whether you intend to create another subject visit right away.

This document is proprietary and is protected by U.S. and international copyright laws and trade secret laws. Copyright © 2021 TransPerfect International, Inc. (TransPerfect). All rights reserved. No part of this document may be reproduced, copied, adapted, modified, distributed, transferred, translated, disclosed, displayed or otherwise used by anyone in any form or by any means without the express written authorization of TransPerfect Senior Management and/or Product Management. Other names may be trademarks of their respective owners.

		Stee & Subject Besh-961 122450 Subject Visits	Search Q
		Subject Visits	
	° L	O Add Week 2 Fills: 2 Deleter	▼ Filters
		1 Visits total	6
	123456 Bash-961	Visit Date Status SDV Date Visit Type Notes	OPEN
		12 Sep 2021 Cycle 2	
	i Subject Details	Create Subject Visit	
	Subject Visits		
		Subject	
		123456	
		Visit Type*	
		Visc Date** SDV Date	
		(day month year 🛗 (day month year 🗂	
		Notes	
		Visit out of Window O*	
		YES NO	
		Cancel Create and Add Another Create	
٠			
T			
6			

5.25 Editing a Subject Visit

- 1. Navigate to the site whose visit needs to be edited.
- 2. Click on the **Subjects** in the Navigation menu at the left side of the screen.
 - a. This opens the "Subjects" window.
- 3. Navigate to the subject name you want to access and click on it.
- Click on the Subjects Visits in the Navigation menu at the left side of the screen.
 a. This opens "Subject Visits" window.
- 5. Navigate to the Subject visit record you want to edit and Click on the checkbox before the Subject visit name.
 - a. A quick view panel will display on the right side of the screen.
- 6. Now, click on the **Edit** button (pencil icon) in the top-right of the screen.
- 7. Make any necessary changes to the subject visit information.
- 8. Click on the Save button in the right bottom of the screen.



5.26 Reviewing and Tracking Country Details

- 1. Navigate to the country whose details you wish to edit.
 - a. This can be done via the navigation menu at the left side of the screen.
- 2. Navigate to the country in the list you want to edit and click on it.
 - a. This opens the dashboard for the country.
- 3. Click on the **Country Details** in the Navigation Menu at the left side of the screen.
 - a. This opens the "Country Details" window.
- 4. Navigate to the section you want to review in the screen and click on the [+] sign next to the name to expand it.
- 5. Click on the **Edit** button on the top-left of the screen to make any changes and before returning, click on the **Save** button for the changes to apply.

TI CTMS USER GUIDE v1.2

	Study KingDerm1 ▼	Study Country United States Country Details	Search Q. 📣 🗸
	• <u>д</u>	United States	S Edt Husory
	United States	Country Information	۵
	i Country Details	Country Management	
	Country Declars Deshboard Milestones	Subject and Recruitment	
	 Sites Subjects 	Informed Consent	8
	Organizations Contacts Team		
	Activities		
=			
٠			
T			

5.27 Tracking Country Informed Consents (ICFs)

- 1. Click on **Countries** in the Navigation menu at the left side of the screen.
- 2. Navigate to the country in the list you want to edit and click on it.
 - a. This opens the dashboard for the country.
- 3. Click on the **Country Details** in the Navigation Menu at the left side of the screen.
 - a. This opens the "Country Details" window.
- 4. Click on the [+] sign next to the informed Consent to expand the section.
- 5. Click on the **Add** button in the informed consent section.
- 6. Click on the dropdown in the **Name** field.
 - a. Study level ICF is displayed and a country specific ICF can be created.

	☆ Study KingDerm1 +	Study Country Country Details Country Details	Search Q. 🗛 🗸
	• A United States	United States Feet * ExpandAl Country Information	🛪 Edit History
	i Country Details	Country Management	e
	Country Decilies Country Dec	Subject and Recruitment	e
	au = 2 subjects Subjects Organizations Contacts € Team Team Activities Activity Plans	Informed Consent	
۰			
T			

- 7. Select the study ICF from the list and click on the save button in the informed consent section.
- 8. You can add country level ICF by adding name and effective date in the informed consent section and click on the save button.

	KingDerm1 •	United States * Country Details		- 🗠
«		United States		
		✓ Eds. w Expand AI		D Edit History
U	Jnited States	Country Information		۲
		Country Management		۲
ß	Dashboard	Subject and Recruitment		۲
Ł	Subjects	Informed Consent		•
	Contacts	Save D Cancel	Q Search	
ė.	Activities	0 Informed Consents		
	Activity Plans			
		Start typing to create a Country-specific informed Consent Q,		
		Study available Initial Protocol ICF Template		
	「「「「「」」「「」」「「」」「」」「「」」「」」「」」「」」」「」」」」」」		Junited States Junited States Country Information Country Management Country Management Subject and Recruitment Subject and Recruitment Subject and Recruitment Informed Consent Country Paris	✓ Site * Expend# United States ✓ Contry Information Country Management Country Management Subject and Recruitment Subject and Recruitment Consent Consent



5.28 Creating Site within a Country

- 1. Click on **Countries** in the Navigation menu at the left side of the screen.
- Navigate to the country in the list you want to edit and click on it.
 a. This opens the dashboard for the country.
- 3. Click on the **Sites** link in the Navigation menu at the left side of the screen.
- 4. Click on the **Add** button in the top-left of the screen.
 - a. This opens the "Create Site" window.
- 5. Fill in the required information and click Create.
 - a. More detailed instructions regarding this step can be found here.

		⊘ Study Country United States ▼			Search Q 🗛 🗸
	×д				
	United States	All Sites Active Closed			Q Search Titers
	onited states	2 Sites	Create Site in United States	• *	
	1 Country Details	Name Stat	General Information Study* KingDerm1	Region	Completed Milestone
	Milestones Sites Subjects Organizations	Binner	This is a satellite site		
	Contacts Team Activities		Size Name	0	
	Activity Plans		Site Organization*	~	
			Cwner® admin admin		
			Status [®] Status Date [®] New O V 20 Sep 2021	<u>(</u>)	
			Cancel Crease and Add Another Crease		
•					
Ť					

5.29 Associating an Organization with a Country

- 1. Select **Countries** from the menu at the left side of the screen.
- 2. Click on the name of the country to which you wish to associate an organization.
- 3. Click on the Organization link in the Navigation menu at the left side of the screen.
- 4. This open the organization window, and organization list is displayed.
- 5. Click on the Add button in the top-left of the screen.
 - a. This opens Add Organization window.
- 6. Search for an Organization or create a new one if necessary.
 - a. More detailed instructions for this step may be found <u>here</u>.

		Study Country Organizations Organizations	Search Q. 🔊 🗸
	• J	Organizations	Q Seach Y Filters
	United States	e organizations Nerve Stell	Primary Contact
	Country Details Dearboard Dearboard Subjects Country Details Subjects Country Details Subjects Team Activity Plans	Q. Search for the Organizations General Information Number* Prenet Organization Ype* Search* Active Phone Numbers O Add Nors Cancel Select and Add Another Cancel Select and Add Another Cancel	
Ť			

5.30 Associating Contacts with a Country

T R I A L INTERACTIVE

- 1. Navigate to the country to which you wish to associate a contact.
- 2. Click on the name of the country to which you wish to associate a contact.
- Click on the Contacts link in the Navigation menu at the left side of the screen.
 a. This opens the "Contacts" window, and contacts list is displayed.
- 4. Click on the **Add** button in the top-left of the screen.
 - a. This opens the "Create Contact in Country" window.

Note: Search field can be used to locate and select existing CTMS contacts.

- Here we need to enter the mandatory metadata to create a contact i.e., Organization, First Name, Last Name, Contact Role, Email Address, Status, Start Date as indicated by an asterisk (*) symbol next to the field title. Enter any additional information, as necessary.
- 6. If any of the required fields are missing, an error will appear when we click on the **Create** button, displaying the fields which need to be filled to create a contact successfully.
- 7. Finally, before clicking **Create**, verify all the fields are entered correctly in the create contact window.
- 8. Create contact in country window closes, contact record is created and displayed in the list.
- 9. (Optional) Click **Create** or **Create and Add Another** depending on whether you intend to create another contact right away.

This document is proprietary and is protected by U.S. and international copyright laws and trade secret laws. Copyright © 2021 TransPerfect International, Inc. (TransPerfect). All rights reserved. No part of this document may be reproduced, copied, adapted, modified, distributed, transferred, translated, disclosed, displayed or otherwise used by anyone in any form or by any means without the express written authorization of TransPerfect Senior Management and/or Product Management. Other names may be trademarks of their respective owners.

TI CTMS USER GUIDE v1.2

		Study Country United States Contacts					Search Q.
	·	Contacts					
		🖸 Add 🖉 Edit 🖓 Remove					Q Search
		0 Contacts	Create Contact in Country	- ×			0
	United States	Name Status			Phone	Start Date	End Date
			Q Search for Contacts	0			
	1 Country Details		General Information	_			
	Deshboard Milestones			~			
	Sites		Prefix First Name* Middle Name	_			
	Subjects Organizations						
2 2	Contects		Lass Name*	Suffix			
	Activities		Job Title Contact Role*				
	Activity Plans		Email Address* Scaus*	~			
			Active	× 1			
			Stort Date End Date day month year				
			Phone Numbers	_			
			O Add				
Value			Cancel Create and Add Another Create				
٠							
T							
6							

6 Site Visit Documentation

Site visits and can be set up so that they trigger specific site-related events directly in an associated eTMF room. This can include generating placeholders for required documentation associated with the site. For more information about configuring your CTMS to work with Trial Interactive's eTMF solution, please reach out to your Trial Interactive representative.

6.1 Pre-Requisite

The user who is responsible for creating and managing **Site Visit Documentation** in an **Organization** must have **Clinical Regulatory Associate** user access.

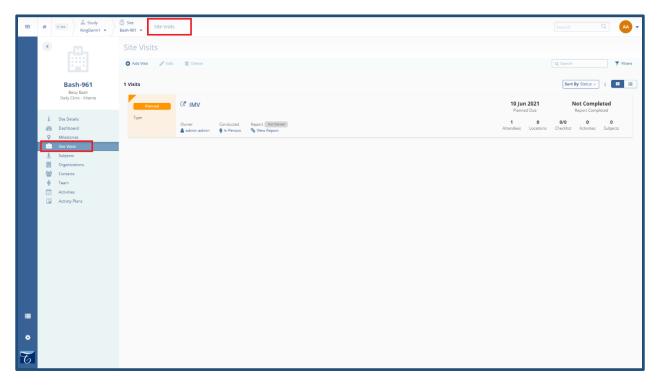
Unblinded users will have the right to create unblinded site visits and related documentation which will only be visible to other unblinded personnel.

6.2 Navigation to Site Visit

- 1. Click on the **Studies** link in the Navigation menu in the panel at the left side of the screen.
 - a. This opens the "Studies" window.



- Navigate to the Study you want to review site visits for and click on the name field.
 a. This opens the dashboard for the study.
- Click on the Sites link in the Navigation menu at the left side of the screen.
 a. This opens the "Sites" window.
- 4. Navigate to the site you want to review site visit for and click on the Name filed value.
 - a. This opens the dashboard for site.
- 5. Click on the **Site Visits** in the Navigation menu in the panel at the left side of the screen.
 - a. This opens the "Site Visits" window.



- 6. Navigate to the Visits you want to review and click on it.
 - a. This opens the Visit General Information window.
- 7. Review the site visit information and make any necessary changes if required and click on the **Save** button in the bottom of the screen, for the changes to apply.

		Bash-961 ▼ Site Visit	Visit General Information					Search Q 📣 🗸
		IMV						(Harred)
								D Edit History
	IMV	Visit Information	ı					
		Visit Type*	~	Visit Status*	0 ~	Duration +Hou	rs Døys	
	Visit General Information Visit Attendees	Visit Name*		- Hinted				
	Locations Visit Checklist	Owner*		Visit Planned Date*				
	0 Activities	Visit Start Date	4	10 Jun 2021 Visit End Date	m)			
	Subjects	day month year	m	day month year	m			
	Enrollment Summary Visit Report O Confirmation Letter	How Was The Visit Conducted*	~	Visit Checklist Templa	*)			
	Commission Letter Follow-Up Letter	Visit Report						
		VISIC Report			Report Status			
					Not Started	~]	Reviewer	
					Status Date			
		2		9	6/22/2021			
		M		te Draft Report				
			Genera	te Dratt Report				
=								
۰								
T		(Previous Step			• Add Activity	inges 🗸 Save 🗸 Save and Next		Next Step >

6.3 Site Visit Attendees

T R I A L INTERACTIVE

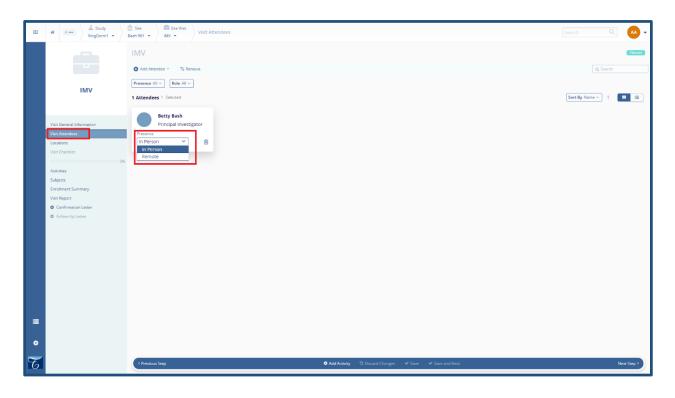
- 1. Navigate to the Site Visit area for the related site.
 - a. More detailed instructions on this step can be found <u>here</u>.
- 2. Click on the Visit Attendees link in the Navigation menu at the left side of the screen.
 - a. This opens the "Visit Attendees" window.
- 3. Click on the Add Attendee button in the top-left of the screen.
- 4. Click on the **Add Attendee** from the dropdown of "Add Attendee" button.
 - a. This opens the "Add Attendees" window.
- 5. Select an existing site contact and click on **Add** button in the bottom of the Add Attendees window.
 - a. Attendee is added to the visit report and the "Add Attendees" window is closed.

Note: Clicking **Create New** will create a new/additional site contact.

T R I A L INTERACTIVE

		Bash Pot → Max Fact Vise Max + Visit Attendees	Search Q A
		IMV	Pervel
		O Add Attendee Si Bronove O Add Attendee Si Attendee A create New Ge All V	Q, Search
	IMV	1 Attendes 1 Selected	Sort By Name ~ 📰 📰
	Visit General Information Visit Attendees Locations Visit Checklist	Betty Bash Principal Investigator Presence In Person	
	0% Activities Subjects		
	Enrollment Summary Visit Report O Confirmation Letter		
	O Follow-Up Letter		
=			
٠			
T		4 Previous Step Q Add Activity [™] D Docard Charges [™] Save [™]	Next Step >

6. We can also the review the **presence** of the Attendee and make any changes if required.





6.4 Site Visit Locations

- 1. Navigate to the Site Visit area for the related site.
 - a. More detailed instructions on this step can be found <u>here</u>.
- 2. Click on the Locations link in the Navigation menu at the left side of the screen.
 - a. This opens the "Locations" window.

Note: If the visit was stated as being conducted remotely, a location will not be required to generate a final visit report.

- 3. Click on the **Add Location** button in the top-left of the screen.
- 4. Click on the **Add Location** from the dropdown of the "Add Location" button.
 - a. This opens the "Add Locations" window.

Note: Clicking Create New will create a new/additional site address.

- 5. Select an existing location and click on the **Add** button in the bottom of the "Add Locations" window.
 - a. Location is added to the visit report and the "Add Locations" window is closed.

		ash-961 → IMV → Locations		Search 🔍 📣 🗸
		IMV		Flowed
		Add Location ~		
	IMV	0 Locations		
	Visit General Information			-
	Visit Attendees	Add Locations	•	×
	Locations Visit Checklist	The Selected Locations 1		
	0%	Previous Locations 0 1 Locations		
	Activities Subjects	All Site Locations 1 Organization Name	Address Type Address	
	Enrollment Summary	Daily Clinic - Atlanta	Institution 🚽 1455 Parkway Cafe, Lincoln Parkway East, Atl	
	Visit Report Confirmation Letter			
	O Follow-Up Letter			
			Cancel Add 1 Locations	
=				
۰				
T		< Previous Step	O Add Activity D Discard Changes ✓ Save ✓ Save and Next	Next Step >

6.5 Site Visit Activities

- 1. Navigate to the Site Visit area for the related site.
 - a. More detailed instructions on this step can be found <u>here</u>.



- Click on the Activities link in the Navigation menu at the left side of the screen.
 a. This opens the "Activities" window.
- 3. Click on the **Add** button in the top-left of the screen
- 4. Click on the Add Activities from the dropdown of the Add button.a. This opens the "Add Activities" window.
- 5. Select an existing site activity from the list of All Site Activities.
- 6. Click on the **Add** button in the Add Activities window.

Note: Clicking Create New will create a new activity for the site.

		3 Site ash∙961 ▼ IMV ▼ Activities			Search Q	AA •
		IMV Activities				Florence
	IMV	Add Add Fdit Remove Add Add Fdit				T Filters
≡ ≎	Vist General Information Visis Chesolise Visis Chesolise Subjects Erredinent Summary Visis Report © Confirmation Letter © Follow-Up Letter	Activities Activities Type Add Activities 0 Previous Visit 0 All Site Activities 0 Activities 0 Activities 0 Activities 0 Activities 0 Activities 0	Sittine Description Owner	Reportable X	Planned Date Completed	
C		< Previous Step	● Add Activity つ Discard Changes ✓ Save ✓ Save and Next		N	ext Step >

Note: When a previous visit has occurred a user can select **Previous Visit** to select Activities that were associated with the previous visit report.

6.6 Site Visit Subjects

- 1. Navigate to the Site Visit area for the related site.
 - a. More detailed instructions on this step can be found <u>here</u>.
- 2. Click on the Subjects link in the Navigation menu at the left side of the screen.
 - a. This opens the "Subjects" window.
- 3. Click on the **Add** button in the top-left of the screen.
- 4. Click on the Add Subject from the dropdown of the Add button
 - a. This opens the "Add Subjects" window.



- 5. Select an existing site subject from the list of All Site Subjects.
- 6. Click on the Add button in the Add Subjects window.

Note: Clicking Create New will create a new subject for the site.

		☐ See == See Vac Beah-961 + IMV + Subjects	Search Q 🗛 🗸
		MV O Ada ✓ ✓ Edit S Remove ⊠ Verly	Q, Search T Filters
	IMV	1 Subjects I Selected Subject ID Status Soreening Number Subject Initials Verified K/Fs verified Subject Virits	10012021
		Image: Weight and Wei	01 Oct 2021 Subject Info Verification Subject Visits
	Visit General Information	Add Subjects	C Informed Consent - History
	Visit Attendees	Selected Subjects 0	Subject History
	Visit Checklist	Readours Ste Visit Subjects 0	Current Status
	Ol6 Activities	All Site Subjects 1 Subjects 0 Status Screening Number Subject Initials Notes	Name Date
	Subjects Enrollment Summary	. 10012021 Sourced	CURRENT STATUS UT OCC 20/21
	Visit Report		Screening Fallure Reason (0)
	Confirmation Letter Follow-Up Letter		
			Early Termination Reason (0)
		Cancel Add D Subjects	
			Summary Information
			Notes
=			
•			Subject Outcome
			subject outcome
C		Previous Step O Add Activity O Discard Charges I Save I Save and Next	Next Step >

Note: When a previous visit has occurred a user can select **Previous Visit** to select subjects that were associated with the previous visit report.

- 7. Add Subjects window is closed, and the subject is displayed in the list.
- 8. To Verify navigate to the subject and click on the check box before subject ID field value.
- 9. Click on the **Verify** button in the top-left of the screen.
 - a. This opens "Subject Verification" window.
- 10. Select a subject visit to verify during the site visit.
- 11. Click on the Go to ICFs button in the bottom on the subject verification window.
- 12. Select an ICF to verify and click on the Save button.

TI CTMS USER GUIDE v1.2

		internet Ster Visit Bash-961 ↔ IMV ↔	Subjects	Search Q.
		IMV O Add ∽ 🖌 Edit 👒 P	kemove 🖾 Verify	Planet Q. Search T Filters
	IMV	Subject 10012021 V	erification Stept • • •	record
	Visit General Information Visit Attendees Locations	icrs.	ct Visits to Add to Report VisitDates	0ic 2021 <u>t linfo</u> Verification Subject Visits formed Consent History ct History
	Visr Checkler Actuates Subgrea Errolineer Summary Visr Report © Confirmation Letter © Talloue-Up Letter		Viait Date I Viait Sanua SDV Date Viait Type Viait Notes Subject Viait Comments	nt Status
			Cancel Go to KF Sour Subject Nex Subject Nex Subject	•
•				Subject Outcome
T		C Previous Step	● Add Activity ¹ D Discard Changes v ⁴ Save v ⁴ Save and Next	Next Step >

6.7 Site Visit Enrollment Summary

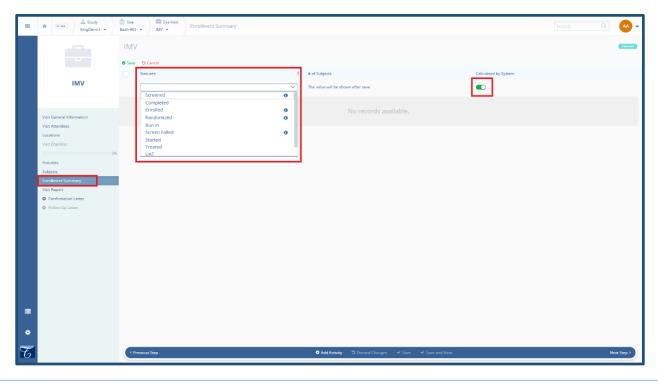
- 1. Navigate to the Site Visit area for the related site.
 - a. More detailed instructions on this step can be found <u>here</u>.
- 2. Click on the Enrollment Summary link in the Navigation menu at the left side of the screen.
 - a. This opens the "Enrollment Summary" window.
- 3. Click on the **Add** button in the top-left of the screen.

		Image: State Visit Image: State Visit Bash-961 - V Image: State Visit Description Enrolliment Summary	Search Q. A. •
		IMV ▼ Add	600
	IMV	Satures 1 ≢ofSubjects No records available.	Calculated by System
	Visit General Information Visit Attendees Locations Visit Checklist		
	0k Activities Subjects Enrollment Summary		
	Visit Report O Confirmation Letter O Follow-Up Letter		
•			
T		Chrokos Sep Okd Ashley Discord Charges V See	≪ Seve and Next Next Step >

4. Select the subject Statuses from the dropdown.

T R I A L INTERACTIVE

5. Indicate if the system should calculate the enrollment statistic or should it be manually entered by the visit report author.





- 6. Click on the **Save** button in the top-left of the screen.
 - **Note**: By turning off **Calculated by System**, the system will allow the user to manually enter the site's enrollment statistics for the site at the time of the site visit.

6.8 Site Visit Confirmation Letter Creation

- 1. Navigate to the Site Visit area for the related site.
 - a. More detailed instructions on this step can be found <u>here</u>.
- 2. Click on the **Confirmation Letter** link in the Navigation menu at the left side of the screen.
 - a. This opens the "Generate Confirmation Letter" window.

Note: Confirmation letter content will be based on the visit preparation data selected.

- 3. Review the sections within the confirmation letter that are relevant
- 4. Click on the **Next** button in the bottom of the **Generate Confirmation Letter** window.
 - **Note**: A user can turn off any section that is not relevant to a visit related confirmation letter. Regardless of user selection/incorporation a letter will only display content that there is a location within the template to display that data.

	#	Ä Study KingDerm1 ♥	📳 Site Bash-961 💌	Site Visit	Confirmation	etter							Sear	ch	Q	•
			IMV													Perved
		Generate Confirma			mation Let	er						Step 1 • • • • • • 🗖 🗙				
	Select Sections Select Activities		Selec	sectio	ns to be included in confirr	nation letter										
	Visit General Info	rmation	Select Atte		Activi											
	Visit Attendees		Select Loca	ations	Locat											
	Visit Checklist		Select Subj	ects	Subje	ts										
	Activities Subjects															
	Enrollment Sumr	nary														
	Visit Report Confirmation 	Letter														
	O Follow-Up Let	ter														
								Cancel	Next							
=			_	_	_						_					
•																
T			< Previou:	s Step				O Add Ac	tivity 🏷 Discard Cha	inges 💙 Save	✓ Save and Next.				Nex	tt Step >

- 5. Click on the **Create** button in the bottom of the **Generate Confirmation Letter** window, once all the selections are made for the letter.
- 6. This generates the site visit confirmation letter as per our selections.

This document is proprietary and is protected by U.S. and international copyright laws and trade secret laws. Copyright © 2021 TransPerfect International, Inc. (TransPerfect). All rights reserved. No part of this document may be reproduced, copied, adapted, modified, distributed, transferred, translated, disclosed, displayed or otherwise used by anyone in any form or by any means without the express written authorization of TransPerfect Senior Management and/or Product Management. Other names may be trademarks of their respective owners.



6.9 Site Visit Draft Report Generation

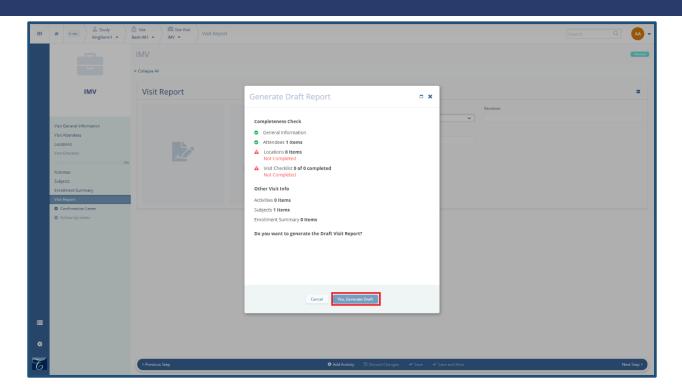
- 1. Navigate to the Site Visit area for the related site.
 - a. More detailed instructions on this step can be found <u>here</u>.
- 2. Click on the Visit Report link in the Navigation menu at the left side of the screen.
 - a. This opens the "Visit Report" window.
- 3. You can update the **Report Status** to **In Progress** and click on the **Save** button.

		Image: Site Image: Site Visit Bash-961 ▼ IMV ▼		Search Q AA -
		IMV		Farred
		* Collapse All		
	IMV	Visit Report		•
	Visit General Information Visit Attandees Locations Visit Checklost OV Activities Subjects	Generate Draft Report	ReportStatun Not Started in Progress Status Union 6/22/2021	
	Errollment Summary Visit Report O Confirmation Letter			
	O follow-Up Lenser			
•				
T		(Previous Step	O Add Activity ⊃ Discard Changes ✓ Save ✓ Save and Next	Next Step >

- 4. Click on the Generate Draft Report button in the screen.
 - a. This opens the "Generate Draft Report" window.
- 5. Click on the Yes, Generate Draft button in the bottom of the window.

This document is proprietary and is protected by U.S. and international copyright laws and trade secret laws. Copyright © 2021 TransPerfect International, Inc. (TransPerfect). All rights reserved. No part of this document may be reproduced, copied, adapted, modified, distributed, transferred, translated, disclosed, displayed or otherwise used by anyone in any form or by any means without the express written authorization of TransPerfect Senior Management and/or Product Management. Other names may be trademarks of their respective owners.

TI CTMS USER GUIDE v1.2



6. It shows as Generating Draft Report please wait when we click on Yes, Generate Draft button.

	# < •••	⊥ Study KingDerm1 ▼	📳 Site Bash-961 💌	Site Visit	Visit Report								Search	Q	•
	_		IMV	IMV											Ranned
			A Collapse All	A Collepse All											
	IMV		Visit	Report											•
							Report Status			Revi	wer				
	Visit General Inf Visit Attendees	ormation					Not Started Status Date			~					
	Locations Visit Checklist				Ĩ		6/22/2021								
	Activities	Q	96		Generating Draft Report										
	Subjects Enrollment Sum	mary		l	Please wait										
	Visit Report Confirmation	Letter													
	O Follow-Up Le	tter													
*			_												
T			< Previou:	s Step			Add Activity	C Discard Changes	✓ Save ✓ Save and Next					Ne	t Step >

7. Draft visit report is generated, and origami is opened displaying the draft report.



6.10 Site Visit Final Report Generation

- 1. Navigate to the Site visit area for the related site.
 - a. More detailed instructions on this step can be found <u>here</u>.
- Click on the Visit Report link in the Navigation menu at the left side of the screen.
 a. This opens the "Visit Report" window.
- 3. Click **Generate Report** in the visit report window.
 - a. This open the "Generate Visit Report" window
- 4. Click on the Yes, Generate button in the Generate Visit Report.

Note: A final visit report can be routed through the submission/review/approval process within origami.

6.11 Site Visit Follow-up Letter Creation

- 1. Navigate to the Site Visit area for the related site.
 - a. More detailed instructions on this step can be found <u>here</u>.
- 2. Click on the Follow-up Letter link in the Navigation menu at the left side of the screen.
 - a. This opens the Follow-up Report window.

Note: Follow-up letter content will be based on the final visit report data selected.

- 3. Review the sections within the confirmation letter that are relevant.
- 4. **Generate Follow-up Letter** window displays the selected sections and the selected content from the final report
- 5. Click on the **Next** button on the screen.

Note: A user can turn off any section that is not relevant to a visit related follow-up letter. Regardless of user selection/incorporation a letter will only display content that there is a location within the template to display that data.

- 6. Click on the Create button of the window.
- 7. Follow-up letter is generated, and origami is opened displaying the letter

7 Product

7.1 Creating a Product

- 1. Click on the **Product** link in the Navigation menu at the left side of the screen.
 - a. This opens the "Products" window, and the products list is displayed.

This document is proprietary and is protected by U.S. and international copyright laws and trade secret laws. Copyright © 2021 TransPerfect International, Inc. (TransPerfect). All rights reserved. No part of this document may be reproduced, copied, adapted, modified, distributed, transferred, translated, disclosed, displayed or otherwise used by anyone in any form or by any means without the express written authorization of TransPerfect Senior Management and/or Product Management. Other names may be trademarks of their respective owners.

Products							Search Q A
C	Products						
Ŧ	🗘 Add 🥒 Edit 🔹 Delete						Q Search Tilter
	33 Products						
	Product	Programs	Status	Туре	Modifier	Owner	Sponsor
TrialInteractive	WWMedocort		Planned	Medicinal	🚢 admin admin	👗 admin admin	Winning World Medicine
🚱 Dashboard	Wisenanol		Planned	Palliative	🛔 admin admin	🛔 admin admin	Wiser Meds
Sponsors	TestUAT004		Planned	Combination	🛔 admin admin	🛔 admin admin	A+ Drugs
Programs	TestUAT		Planned	Vaccine	🛔 admin admin	🛔 admin admin	Dermeron
Products Studies	Gastrotube		Parred	Device	🛔 admin admin	👗 admin admin	Gastroclean Inc
Organizations	MedicalImmune Patch	🖹 MI Patch	Planned	Custom	📥 system system	🛔 admin admin	. Medical Immune
Contacts	Integucaine	▲ Integ_IV	Active	Palliative	🛔 system system	🛔 admin admin	Dermeron
User Management	Scotts Wash		Planned	Combination	🛔 system system	🛔 admin admin	Scott Works
Activity Plan Templates	MMGyn	<u>di 2</u>	Active	Diagnostic	🛔 system system	🛔 admin admin	May & May Pharmaceutical
Milestone Templates	WorkIMP4	الله الله الله الله الله الله الله ا	Planned	Diagnostic	🛔 system system	🛔 admin admin	Working 4U
	Diagnova	🖹 Diagnova321	Planned	Medicinal	🛔 system system	🚔 Steven Clark	A+ Drugs
	MMGenerics	<u>d 2</u>	Planned	Custom	🛔 system system	🛔 admin admin	May & May Pharmaceutica
	🔲 🏛 ммов	<u>di</u> 2	Planned	Custom	📥 system system	🛔 admin admin	May & May Pharmaceutical
	MMEar	<u>d</u> 2	Active	Device	🛔 system system	🛔 admin admin	May & May Pharmaceutical
	MMEye	<u>a</u> 2	Planned	Diagnostic	🛔 system system	🛔 admin admin	May & May Pharmaceutical
	MMDental	<u>di 2</u>	Planned	Custom	🛔 system system	🛔 admin admin	May & May Pharmaceutical
	MMOrtho	<u>a</u> 2	Active	Device	🛔 system system	🛔 admin admin	📕 May & May Pharmaceutical
	MMCardio	<u>d</u> 2	Planned	Device	🛔 system system	🚨 admin admin	📕 May & May Pharmaceutical
	MMAllergy	<u>at 3</u>	Planned	Custom	🛔 system system	🛔 admin admin	May & May Pharmaceuticals
	MMVax	<u>d</u> 2	Planned	Vaccine	🛔 system system	🚨 admin admin	📕 May & May Pharmaceuticals
	MMPeds	<u>at</u> 2	Planned	Custom	🚔 system system	🚢 admin admin	📕 May & May Pharmaceuticals

- 2. Click on the **Add** button in the top-left of the screen.
 - a. This opens the "Create Product" Window.
- Here we need to enter the mandatory metadata to create a product i.e., Product Name, Type, Status, Status Date, Sponsor as indicated by an asterisk (*) symbol next to the field title. Enter any additional information, as necessary.
- 4. If any of the required fields are missing, an error will appear when we click on the **Create** button, displaying the fields which need to be filled to create a product successfully.
- 5. **(Optional)** Click Create or **Create and Add Another** depending on whether you intend to create another product right away.

*	Products									Search Q
		0/	Add 🥒 Edit 🏦 Delete							Q Search
	()		Products							
		33 P	Product	Programs	Status	Туре		Modifier	Owner	Sponsor
	TrialInteractive		WWMedocort		Planed	Medicinal		admin admin	🛔 admin admin	Winning World Medicine
			A Wisenanol		Create Product		×	🛔 admin admin	🚨 admin admin	Wiser Meds
	Dashboard Sponsors		TestUAT004					admin admin	🛔 admin admin	A+ Drugs
	Programs		E TestUAT		Product Name*	Type*	~	🚢 admin admin	🛔 admin admin	Dermeron
-	Products Studies	- 0	Gastrotube		Status*	Status Date*		admin admin	admin admin	Gastroclean Inc
	Organizations		MedicalImmune Patch	💰 MI Pate		23 Sep 2021		System system	🚔 admin admin	Medical Immune
	Contacts		🚔 Integucaine	å Integ_i	Sponsor*			a system system	🚔 admin admin	Dermeron
	User Management		Scotts Wash				~	🚔 system system	🛔 admin admin	Scott Works
	Activity Plan Templates		🚔 MMGyn	<u>2</u>	Indications 0 Indications Select			🛔 system system	🛔 admin admin	📕 May & May Pharmaceuti
	Milestone Templates		WorkIMP4	🖄 WorkP				System system	🛔 admin admin	Working 4U
			🚔 Diagnova	🖄 Diagno				🚔 system system	🛔 Steven Clark	A+ Drugs
			MMGenerics	<u>a</u> 2	Description			System system	👗 admin admin	May & May Pharmaceuti
			🚔 ммов	<u>a</u> 2				🚔 system system	🛔 admin admin	📕 May & May Pharmaceuti
			🚔 MMEar	<u></u> 2	Cancel Create and	Add Another Create		🛔 system system	🛔 admin admin	May & May Pharmaceuti
			🚔 MMEye	<u>2</u>	Cancer	Create		🚢 system system	🚔 admin admin	May & May Pharmaceuti
			MMDental	<u>2</u>	Planned	Custom		System system	admin admin	May & May Pharmaceuti
			MMOrtho	<u>2</u>	Active	Device		🛔 system system	🚨 admin admin	May & May Pharmaceuti
			AMMCardio	<u></u> 2	Planned	Device		🚨 system system	🚨 admin admin	May & May Pharmaceuti
			AMMAllergy	a 3	Planned	Custom		a system system	着 admin admin	May & May Pharmaceuti
			🚔 MMVax	<u>at</u> 2	Planned	Vaccine		🛔 system system	🚨 admin admin	May & May Pharmaceutic
			AMMPeds	2	Planned	Custom		🛔 system system	👗 ədmin ədmin	May & May Pharmaceutic

7.2 Reviewing and Editing a Product

- 1. Click on the **Product** link in the Navigation menu at the left side of the screen.
 - a. This opens the "Products" window, and the products list is displayed.
- 2. Click on the name of the product you want to edit.
 - a. This opens the "Product Details" window.
- 3. Click on the **Edit** button in the top-left of the screen.



TI CTMS USER GUIDE v1.2

	Product MedicalImmune Patch +	Product Details			Search Q A
	•	✓ Edit A Collapse All			Edit History
		Product Information			-
	MedicalImmune Patch	Product Name Medicalimmune Patch		Regulatory Identifiers	•
	1 Product Details	Sponsor Medical Immune			
	Programs	Owner Type admin admin Cu	istom	Indications 0 Indications	
	 Sites Organizations Contacts 	Status Date Planned 07 Sep 2021	Change Status		
		Status Notes		Description	
				Notes	
			Status History	Notes	
		IND			
		Drug Safety Code			
*					
T					

- 4. Make the necessary changes in the product details window.
- 5. Click on the **Save** button in the top-left of the screen.

	Product MedicalImmune Patch •	Product Details	Search Q 🗛 🗸
	•	C Sure Caccel A Collapse All	S Edit Hanoy
	MedicalImmune Patch	Product Information Product Name* Medicalimmune Patch Sponser*	Regulatory identifiers
	Product Details Programs	pointor Medical Immune Consorted V	Indicasions 9 Indications
	Studies Sites Organizations Contacts	admin admin Custom Satus Satus Date Panned 075ep 2021	Select
		Sanus Notes	Description
		D Satur History NO	
		Drug Safety Code	
=			
ہ ح			



7.3 Associating an Organization to a Product

- 1. Click on the **Product** link in the Navigation menu at the left side of the screen.
 - a. This opens the "Products" window, and the products list is displayed.
- Click on the name of the Product you want to associate to an organization.
 a. This opens the "Product Details" window.
- Click on the Organization link in the Navigation menu at the left side of the screen.
 a. This opens the "Organization" window.
- 4. Click **Add** and either search for an existing organization or create a new one.
- 5. Press **Create** when done.
 - a. More detailed instructions on this step can be found here.

	*	Product MedicalImmune Patch 👻	Organizations			Search	• 🌑
	×						
			🗘 Add 🥒 Edit 🛛 S3 Remove				T Filters
	Medi	calimmune Patch		Add Organization			0
			Name Statu	Q. Search for the Organizations	Subtype	Primary Contact	N
		Product Details		General Information			
	<u>A</u>	Programs Studies		Name*			
		Organizations		Number*			
	100	Contacts		Parent Organization			
				Type* Subtype			
				· · · · · · · · · · · · · · · · · · ·			
				Stanu [®] Active			
				Primary Contact			
				Phone Numbers			
				O Add			
				Notes			
				Cancel Create and Add Another Create			
=							
T							

7.4 Associating a Contact to a Product

- 1. Click on the **Product** link in the Navigation menu at the left side of the screen.
 - a. This opens the "Products" window, and the products list is displayed.
- 2. Click on the name of the product to which you wish to associate a contact.
 - a. This opens the "Product Details" window.
- 3. Click Add and either search for an existing Contact or create a new one.
- 4. Press Create when done.
 - a. More detailed instructions on this step can be found <u>here</u>.

TI CTMS USER GUIDE v1.2

ш	# Product Medicalimmune Patch •	Contacts					[Search: Q] 💊 🗸
	°	Contacts					Q.Search
	MedicalImmune Patch	0 Contacts Name Status	Create Product Contact		Phone	Start Date	End Date
	Image: Product Details Image: Programs Image: Studies Image: Studies		Phone Numbers • Add	Middle Name Suffix Conset Bole* Status* Active Active			
T							

8 Program

8.1 Pre-Requisites

Each Organization will need to decide who should handle Program creation and managing. It may be a specific group of people in the organization who are assigned to handle this to reduce the chances of creating duplicate program records. Company administrators will need to assign CREATE, UPDATE, EDIT and DELETE permissions/privileges to user's accounts to that they can perform this step.

8.2 Create a Program

- 1. Click on the **Programs** link in the Navigation Menu at the left side of the screen.
 - a. This opens the "Programs" window, and the programs list is displayed.

R	Programs				
To	🔿 Add 🥒 Edit 📋 Delete				Q Search T Filte
\bigcirc	20 Programs				
TrialInteractive	Program Name	Status	Number	Sponsor	Product
	TestUATP	Planning	111	Dermeron	Astrogum
Deshboard	Integ_IV	Planving	20211609_1013	Dermeron	incegucaine
Sponsors	MI Patch	Planning	133982021	Medical Immune	Medicalimmune Patch
Programs	MM-One	Planning	928912021	May & May Pharmaceuticals	MMAllergy
Products	MM-Some	Planning	925912021	May & May Pharmaceuticals	a 13
Organizations	MM-ALL	Active	920912021	May & May Pharmaceuticals	(a 14
Contacts	WorkP1	Planning	2108272021	Warking 4U	WorkIMP4
User Management	Diagnova321	Ranning	321	A+ Drugs	2
Activity Plan Templates	abc	Planning	111	ACI Pharmaceuticals	Astrogum
Milestone Templates	MMOnc	Planning	872021359	May & May Pharmaceuticals	MMOnc
	Galashegos524	Planning	#1245524	Galashegos Pharmaceuticals	Dragon Steel
	Mays Limbs	Planning	429-6160	May & May Pharmaceuticals	2
	A+-008	Cloved	008-01	A+ Drugs	2
	RKTrans	Planning	3006142021	RK Meds	TransPure
	C King Peds	Planning	9425122021	Ring Research	Kings Cream
	May & May Vaccines Program	Active	8555112021	📕 May & May Pharmaceuticals	a 3
	May&May Market Device Test	Planning	10184262021	May & May Pharmaceuticals	(à 2)
	King Derma	Planning	11183252021	King Research	Kings Cream
	AstroRA-32021	Planning	132021	Astrovile	â 2
	Wellness Program	Planning	123-1	Morvarty	

- 2. Click on the **Add** button in the top-left of the screen.
 - a. This opens the Create Program window.
- Here we need to enter the mandatory metadata to create a program i.e., Program Name, Number, Status, Status Date, Sponsor, Products as indicated by an asterisk (*) symbol next to the field title. Enter any additional information, as necessary.
- 4. If any of the required fields are missing, an error will appear when we click on the **Create** button, displaying the fields which need to be filled to create a program successfully.
- 5. (Optional) Click **Create** or **Create and Add Another** depending on whether you intend to create another program right away.

Note: Program records can be created in multiple locations within the system:

- 1. Programs
- 2. Sponsors \rightarrow Programs
- 3. Product \rightarrow Programs

TI CTMS USER GUIDE v1.2

1	Programs					Search Q. AA
		🖸 Add 🥒 Edit 🏢 Delete				Q Search Tilte
		20 Programs				
		Program Name			Sponsor	Product
	TrialInteractive	TestUATP	Create Program		Dermeron	Astrogum
		Integ_IV	Program Name*	Number*	Dermeron	
	Dashboard Sponsors	MI Patch	Program Name"	Number	Medical Immune	MedicalImmune Patch
	Programs	MM-One	Status*	Status Date*	May & May Pharmaceuticals	MMAllergy
	Products	MM-Some	Planning	✓ 23 Sep 2021	× 👚 May & May Pharmaceuticals	13
	Studies Organizations	MM-ALL	Sponsor*		May & May Pharmaceuticals	14
	Contacts	WorkP1	Products*		Working 4U	WorkIMP4
	User Management	Diagnova321	Products"		A+ Drugs	2
	Activities Library Activity Plan Templates	abc			ACI Pharmaceuticals	Astrogum
	Milestone Templates	MMOnc			May & May Pharmaceuticals	MMOnc
		Galashegos524	Description		Galashegos Pharmaceuticals	Bragon Steel
		Mays Limbs			May & May Pharmaceuticals	2
		A+-008			A+ Drugs	<u> </u>
		RKTrans			RK Meds	TransPure
		King Peds			King Research	Kings Cream
		May & May Vaccines Program	Cancel	reate and Add Another Create	May & May Pharmaceuticals	
		May&May Market Device Test			May & May Pharmaceuticals	2
		King Derma	Planning	11183252021	King Research	Kings Cream
		AstroRA-32021	Planning	132021	Astrovile	2
		Wellness Program	Planning	123-1	Morvarty	

8.3 Reviewing and Editing a Program

- 1. Click on the Programs link in the Navigation Menu at the left side of the screen.
 - a. This opens the "Programs" window, and the programs list is displayed.
- 2. Navigate to the program you want to review or edit and click on the name.
 - a. This opens the "Program Details" window.
- 3. Click on the **Edit** button in the top-left of the screen.



	*	Program Diagnova321 ▼ Program	n Details			Search Q AA	•
	ĸ		Edit A Collapse All			D Ede Hi	story
			Program Information			•	
		Diagnova321	Number	Program Name	Notes		
			321 Sponsor	Diagnova321			
	i	Program Details	A+ Drugs				
	<u>ش</u> ۵	Products Studies	Description				
	¢	Sites					
	(종) (종)	Organizations Contacts					
	. +	Team	Devis et Marconenet			_	5
			Project Management			•	-
			Status Status Date Planning 25 Aug 20		es		
						Status History	
			Planning Information				ñ
			Number of Planned Studies	Number of Planned Countries	Number of Planned Sites	Number of Planned Subjects	
			0	0	0	0	
							5
			Additional Information			•	
				Number of Program related			
٠				Yes No test			
T							
6							

- 4. Make any necessary changes in the sections you want.
- 5. Click on the **Save** button on the top-left of the screen, for the changes to apply.

	*	Program Diagnova321 • Prog	yam Details	Search Q 🗛 🗸
	*		C Serre Callapse All	S Edit History
			Program Information	-
		Diagnova321	Number* Program Name* Notes 321 Diagnova321 Imit African Africa	
			Spinor*	
	_	Program Details	A+ Drugs Actes	
	 ∡	Products Studies	Description	
	¢	Sites		
	병	Organizations Contacts		
	÷	Team		
			Project Management	•
			Status Status Date Status Notes	
			Mannling 25 Aug 2021 Change Status	Status History
			Planning Information	-
			Number of Planned Studies Number of Planned Countries Number of Planned States	Number of Planned Subjects
			0 0	0
_			Additional Information	•
			Number of Program related products 🖗	
٠			Yes No text YES NO	
T				
6				



8.4 Associating an Organization to a Program

- Click on the **Programs** link in the Navigation Menu at the left side of the screen.
 a. This opens the "Programs" window, and the programs list is displayed.
- Click on the name of the program to which you wish to associate an organization.
- a. This opens the "Program Details" window.
- 3. Click on the **Organization** link in the Navigation menu at the left side of the screen.
- a. This opens the "Organization" window, and the organization list is displayed.
- 4. Click **Add** and either search for an existing organization or create a new one.
- 5. Press **Create** when done.
 - a. More detailed instructions on this step can be found here.

	*	 Program Diagnova321 • 	rations				Search	Q,	AA •	
	×		Organizations							
			🕥 Add 🥒 Edit 🛛 S3 Remove						T Filters	
		Diagnova321	1 Organizations	Add Organization	× □				0 9	
			A+ Drugs	Q. Search for the Organizations	_	Subtype	Primary Contact		EN I	
	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Program Desals Products Studies States Constan Team		Conservation of the organizations	>					
				Primary Canact Phone Numbers O Add Notes Cancel Create and Add Another Create						
•										
T										

8.5 Associating a Contact to a Program

- 1. Click on the **Programs** link in the Navigation Menu at the left side of the screen.
 - a. This opens the "Programs" window, and the programs list is displayed.
- 2. Click on the name of the program to which you wish to associate a contact.
 - a. This opens the "Program Details" window.
- 3. Click on the **Contacts** link in the Navigation menu at the left side of the screen.
 - a. This opens the "Contacts" window, and the contacts list is displayed.
- 4. Click on the **Add** button in the top-left of the screen.
 - a. This opens Create Contact in program window.

This document is proprietary and is protected by U.S. and international copyright laws and trade secret laws. Copyright © 2021 TransPerfect International, Inc. (TransPerfect). All rights reserved. No part of this document may be reproduced, copied, adapted, modified, distributed, transferred, translated, disclosed, displayed or otherwise used by anyone in any form or by any means without the express written authorization of TransPerfect Senior Management and/or Product Management. Other names may be trademarks of their respective owners.

TI CTMS USER GUIDE v1.2

	n	🚔 Program Diagnova321 👻	5					Search Q 🙆 🔹
	×	Diagnova321	Contacts Contacts Nerre Status		• ×	Phone	Start Date	o, Search End Date
		Program Details Products Studies States Organizations Ceremitik Team	I	Prefix First Name* Middle Name Last Name* Suffix Job Tide Contact Role* Email Address* Economic Address Start Date End Date				
• 6				Phone Numbers © Add Cancel Create and Add Another Create				

- 5. Here we need to enter the mandatory metadata to create a Contact i.e., Organization, First Name, Last Name, Contact Role, Email Address, Status, Include Address as indicated by an asterisk (*) symbol next to the field title. Enter any additional information, as necessary.
- 6. If any of the required fields are missing, an error will appear when we click on the **Create** button, displaying the fields which need to be filled to create a contact successfully.
- 7. (Optional) Click **Create** or **Create and Add Another** depending on whether you intend to create another contact right away.

Note: The search bar at the top of the "Create Contact in program" window can be used to search for an existing CTMS contact record for associate to the program.

Note: The system will restrict the level of data that can be updated to only information relevant to the association of the contact to the program. All other data will need to be updated at the Home > Contacts level.



8.6 Associating a Product to a Program

- Click on the **Programs** link in the Navigation Menu at the left side of the screen.
 a. This opens the "Programs window", and the programs list is displayed.
- 2. Click on the name of the program you want to associate to a product.
 - a. This opens the **Program Details** window.
- 3. Click on the **Products** link in the Navigation menu at the left side of the screen.
 - a. This opens the "Products" window, and the products list is displayed.
- 4. Click the **Add** button in the top-left of the screen.
 - a. This opens **Add Product** window.
- 5. Select a product from the available products list.

	*	 Program Diagnova321 • 	S					[Search Q	•
	•									
			🖉 Add 🥒 Edit 🛛 🕄 Remove							▼ Filters
		Diagnova321	2 Products							
		Diagnovaszi	Product	Programs	Status	Туре	Modifier	Owner	Sponsor	
			Diagnova	💰 Diagnova321	Planned	Medicinal	🛔 system system	🛔 Steven Clark	📕 A+ Drugs	
	▲ 合 問 替	Program Details Products Studes Studes Organizations Contacts Team	Azoretia	Add Product Select Product Product Atrogem Atrogem Atrometika Diagrovia Dragon Steel Gastrotube InteguZaine Kings Cream		- X	1		Arrot	
۰										
~										
T										

9 Activities

9.1 Associating Domain library Activity Records to a Study

- 1. Click on the **Studies** link in the Navigation menu at the left side of the screen.
 - a. This opens the "Studies" window.
- 2. Click on the name of the study.
 - a. This opens dashboard for the study.



- Click on the Activity Plans link in the Navigation menu at the left side of the screen.
 a. This opens the "Activity Plans" window.
- 4. Click on **Templates** in the top-left center of the screen.a. This opens the "Templates" window.
- 5. Click on the **Add** button in the top-left of the screen.
 - a. Now click on Associate from the dropdown menu.

	*	Ä Study Diagnova ▼ Activit	ty Plans Templates	Search Q A	•
	«		Activity Plans		
			Plans In Use Scheduled Plans Templates		
		Diagnova	Add - Add - A Edit (1) Copy & Activity Co Activity Co Sector Restred (1) Delete	Q Search T Fil	lters
			O Create mplates	Sort By Unknown ~	
		Study Details Dashboard	No records available		
	9 0	Milestones Countries			
	i i	Sites Subjects			
		Organizations			
	÷	Team Activities			
		Activity Plans			
•					
T					
6					

6. This opens the Associate Activity Plan Templates to study "Study name is displayed".

	#	∆ Study Diagnova ▼	lans Templat	es								Search	<u>م</u>	•
	«		Activity	Plans										
		Diagnova	Plans In U	Assoc	iate Activity Plan	Templates	to Study "Diagnova"			– 3	×			
			0 Available 1		he activity plan templates you	would like to use	for the study					Q Search Sort By Unknown ~		Filters
	8	Study Details Dashboard Milestones			y Study Start-Up ×									
	0	Countries Sites Subjects		6 Activ	ity Plan Templates 1 Selecte									
		Organizations			Plan Name Study Start-Up	Classification Start-up	Description		Level	Activities 2				
	*	Contacts Team			Country Study Start-Up	Start-up	Country EC start-up		🔇 Country	2				
		Activities Activity Plans			Site Start-up Plan	Start-up	Initial Site EC start-up		🛱 Site	2				
		Activity Plans			SSU for Peds 2 Related Plans	Start-up	SSU Pediatric		A Study	2				
					SSU for Peds Country 1 Related Plan				Q Country	1				
					SSU for Peds Site				🛱 Site	1				
_							Cancel							
				_		_		_	_	_				
٠														
T														

- 7. Click on the **check box** before the plan name you want to associate to a study.
- 8. Click on the **Associate** button in the bottom of the **Associate Activity Plan Template**.

9.2 Creating Domain library Activity Records

- 1. Click on the Activities Library link in the Navigation menu at the left side of the screen.
 - a. This opens the "Activities Library" window.
- 2. Click on the **Add** button in the top-left of the screen.
 - a. This opens the Create Activity window.
- 3. Here we need to enter the mandatory metadata to create an Activity i.e., **Activity, Type, Sub Type, Description** as indicated by an asterisk (*) symbol next to the field title.
- 4. Initially Sub Type is greyed out, once you select a value for the Type from the dropdown menu the related values for the sub type will appear in the dropdown menu.
- 5. If any of the required fields are missing, an error will appear when we click on the **Create** button, displaying the fields which need to be filled to create an activity successfully.
- 6. **(Optional)** Click **Create** or **Create and Add Another** depending on whether you intend to create another activity right away.

This document is proprietary and is protected by U.S. and international copyright laws and trade secret laws. Copyright © 2021 TransPerfect International, Inc. (TransPerfect). All rights reserved. No part of this document may be reproduced, copied, adapted, modified, distributed, transferred, translated, disclosed, displayed or otherwise used by anyone in any form or by any means without the express written authorization of TransPerfect Senior Management and/or Product Management. Other names may be trademarks of their respective owners.

TI CTMS USER GUIDE v1.2

*	Activities Library										AA
۲			tivities Library								
	Ŧ	0 4	kdd 🥒 Edit 🏦 Delete 🔷 Set /								T File
	\bigcirc	35 A	ctivities								
	TrialInteractive		Activity Name	Status	Туре	Subtype		Description	Modified	Modifier	
	manneractive		CTMS 1.1 UAT DRY RUN 010_Activity	ACTIVE	Adknowlegement	IRB/EC		CTMS 1.1 UAT DRY RUN 010_TEST Acti	21 Sep 2021	å admin admin	
			CTMS 1.1 UAT DRY RUN 010 - ACTI					ST	21 Sep 2021	🚢 admin admin	
	Dashboard Sponsors		CTMS 1.1 UAT DRY RUN 010 - ACTI	Create	e Activity		• ×	#2	21 Sep 2021	🚢 admin admin	
			🛱 Number 2					cond Activity Approval	17 Sep 2021	🛔 admin admin	
	Products		🗭 Number 1	Activity*]			tivity Acknowledgment	17 Sep 2021	🚨 admin admin	
	Studies Organizations		UAT Authoring Activity		•			thoring	10 Sep 2021	💄 admin admin	
	Contacts		🗇 Anuj	Type*	/al	Subtype*	~	r Anuj to see how the library works.	10 Sep 2021	🛔 system system	
	User Management		🗭 Refrig Log	Descripti				8	10 Sep 2021	🛔 system system	
	Activities Library		Monitoring Schedule definition	Description				finition of visit schedule expected fo	10 Sep 2021	🚨 admin admin	
	Activity Plan Templates Milestone Templates		💆 Zeta Team Agenda					ta TMF Plan meetings agenda	10 Sep 2021	🛔 system system	
			Clinical Monitoring Plan Workshop					orkshop to define the Program moni	10 Sep 2021	🛔 system system	
			Tremor Start-up Survey					tial evaluation of start-up process fo	10 Sep 2021	🛔 system system	
			IRB/EC Submission of Site Closure					e is required to notify the sites gove	10 Sep 2021	🚔 system system	
			Feasibility Questionnaire					tial Study feasibility questionnaire	10 Sep 2021	🚔 system system	
			Receipt Log		Cancel	reate and Add Another Create		g to be checked off and signed by st	10 Sep 2021	🛔 system system	
			觉 Cover Letter	ACTIVE	Communication	Letter		Letter included in shipment detailing s	10 Sep 2021	🛔 system system	
			Patient Brochure	ACTIVE	Document	Protocol		Initial protocol patient brochure for wa	10 Sep 2021	🛔 system system	
			Marketing Introduction letter	ACTIVE	Communication	Email		Letter to sites introducing the marketi	10 Sep 2021	👗 system system	
			Minterest Questionaire	ACTIVE	Communication	Fax		Initial study interest	10 Sep 2021	🔓 system system	
			Destruction supplies communicati	ACTIVE	Communication	Letter		Letter set to site with destruction mate	10 Sep 2021	🛔 system system	
			🛱 Empty ISF Binders	ACTIVE	Document	Protocol		Empty binders for the housing of ISF d	10 Sep 2021	🛔 system system	
			Submission	ACTIVE	Document	Protocol		Submission document of study annual	10 Sep 2021	🛓 system system	

9.3 Editing Domain Library Activity Records

- 1. Click on the Activities Library link in the Navigation menu at the left side of the screen.
 - a. This opens the "Activities Library" window.
- 2. Navigate to the activity name you want to edit and click the check box before the activity name or click directly on the activity name.
- 3. Click on the **Edit** button in the top-left of the screen.
 - a. This opens the quick view panel on the right side of the screen.
- 4. Make necessary changes in the quick view panel.
- 5. Click on the **Save** button in the bottom right of the screen.

Note: Updates to an activity record will not be reflected within activity plans already actively applied or tracking. Updated activity records will be used for any new application or tracking of an activity plan containing the updated record.

TI CTMS USER GUIDE v1.2

(e)	Activities Library						
\sim	🗘 Add 🖉 Edit 🏦 Delet	e 🔷 Set Inactive					Q, Search TR
10	Contraction of the second						a server
\mathbf{O}	35 Activities 1 Selected						🛱 Number 2
TrialInteractive	Activity Name	Status Type	Subtype	Description	Modified	Modifier	General Information
	CTMS 1.1 UAT DRY R_	ACIME Acknowlegeme		CTMS 1.1 UAT DRY RUN 0	21 Sep 2021	🛔 admin admin	
Dashboard	CTMS 1.1 UAT DRYR_	ACIME Acknowlegeme	nt IRB/EC	TEST	21 Sep 2021	admin admin	Activity* Number 2
Sponsors	CTMS 1.1 UAT DRY R_	Approval	Annual Renewal	test2	21 Sep 2021	🛔 admin admin	
Programs	🗹 🖨 Number 2	ACTIVI Approval	Initial	Second Activity Approval	17 Sep 2021	admin admin	Type* Subtype*
Products A Studies	Number 1	ACTMI Acknowlegeme	nt IRB/EC	Activity Advnowledgment	17 Sep 2021	🛔 ədmin ədmin	Description*
Organizations	UAT Authoring Activity	ACTIVE Communication	Letter	Authoring	10 Sep 2021	🛔 edmin edmin	Second Activity Approval
Contacts	🗌 🗑 Anuj	ACTMI Document	ICF Template	For Anuj to see how the li	10 Sep 2021	🛔 system system	
User Management	Refrig Log	RACTIVE Document	Protocol	Test	10 Sep 2021	🛔 system system	
Activities Library Activity Plan Templates	Monitoring Schedule	ACTIVE Meeting	Monitoring Plan	Definition of visit schedul	10 Sep 2021	🛔 admin admin	Associated Plans
Milestone Templates	Zeta Team Agenda	INACTIVE Meeting	TMF Plan	Zeta TMF Plan meetings a	10 Sep 2021	🛔 system system	
	Clinical Monitoring Pl	ACTIVE Meeting					
	Tremor Start-up Surv	ACTIVE Document	Protocol	Initial evaluation of start	10 Sep 2021	🛔 system system	
	IRB/EC Submission o	ACTM Document	Protocol	Site is required to notify t	10 Sep 2021	🛔 system system	
	Feasibility Questionn	ACTIVE Document	Protocol	Initial Study feasibility qu	10 Sep 2021	🛔 system system	
	🔅 🛱 Receipt Log	ACTIVE Document	Protocol	Log to be checked off an	10 Sep 2021	🛔 system system	
	Cover Latter	ACTME Communication	Letter	Letter included in shipme	10 Sep 2021	🛔 system system	
	Patient Brochure	ACTIVE Document	Protocol	initial protocol patient br	10 Sep 2021	🛔 system system	
	Marketing Introducti	ACTME Communication	Email	Letter to sites introducing	10 Sep 2021	🛔 system system	
	📋 💮 Interest Questionaire	ACTIVE Communication	Fax.	Initial study interest	10 Sep 2021	🛔 system system	
	Destruction supplies	Communication	Letter	Letter set to site with des	10 Sep 2021	🛔 system system	
	Empty ISF Binders	ACTIME Document	Protocol	Empty binders for the ho	10 Sep 2021	👗 system system	
	💭 Submission	ACTIVE Document	Protocol	Submission document of	10 Sep 2021	a system system	Cancel Save Save & Next

9.4 Deleting Domain Activity Records

- Click on the Activities Library link in the Navigation menu at the left side of the screen.
 a. This opens the "Activities Library" window.
- 2. Navigate to the activity name you want to delete and click the check box before the activity name or click directly on the activity name.
- 3. Click on the **Delete** button in the top-left of the screen.
- 4. This deletes the Activity record.

Note: The system will restrict the ability to delete an activity record that is being used within the system, the user should inactive such records and not delete them.

TI CTMS USER GUIDE v1.2

ñ	Activities Library									9
		Activities Library								
	Ŧ	🔿 Add 🥒 Edit 📋 De	elete 🗢 Set Ina	tive					Q Search	Ŧ
	\bigcirc	35 Activities 1 Selected							🖄 Number 2	
	TrialInteractive	Activity Name	Status	Туре	Subtype	Description	Modified	Modifier		
	mannerocure	CTMS 1.1 UAT DRY R.	ACTIVE	Acknowlegement	IRB/EC	CTMS 1.1 UAT DRY RUN 0	21 Sep 2021	🛔 admin admin	General Information	
		CTMS 1.1 UAT DRY R.	ACTIVE	Acknowlegement	IRB/EC	TEST	21 Sep 2021	👗 admin admin	Activity	
8	Deshboard Sponsors	CTMS 1.1 UAT DRYR.	NACTIVE	Approval	Annual Renewal	test2	21 Sep 2021	🛔 ədmin ədmin	Number 2	
6		🗹 🛱 Number 2	ACTIM	Approval	Initial	Second Activity Approval	17 Sep 2021	admin admin	Type Subtype	
-		Number 1	ACTME	Acknowlegement	IRB/EC	Activity Adonowledgment	17 Sep 2021	🛔 ədmin ədmin	Approval Initial	
4		UAT Authoring Activit	y ACTIVE	Communication	Letter	Authoring	10 Sep 2021	🛔 admin admin	Description Second Activity Approval	
4		🗌 🗑 Anuj	ACTIME	Document	ICF Template	For Anuj to see how the li-	10 Sep 2021	🛔 system system		
11	User Management	Refrig Log	INACTIVE	Document	Protocol	Test	10 Sep 2021	🛔 system system		
Ē		Manitoring Schedule	ACTIVE	Meeting	Monitoring Plan	Definition of visit schedul	10 Sep 2021	🛔 admin admin	Associated Plans	
0	Activity Plan Templates Milestone Templates	Zeta Team Agenda	PACTIVE	Meeting	TMF Plan	Zeta TMF Plan meetings a	10 Sep 2021	🛔 system system		
		Clinical Monitoring Pl	ACTIVE	Meeting	Monitoring Plan	Workshop to define the P	10 Sep 2021	🛔 system system		
		Tremor Start-up Surv	ACTIVE	Document.	Protocol	Initial evaluation of start	10 Sep 2021	🋔 system system		
		IRB/EC Submission o	ACIME	Document	Protocol	Site is required to notify t	10 Sep 2021	🛔 system system		
		Feasibility Questionn	ACTIVE	Document	Protocol	Initial Study feasibility qu	10 Sep 2021	🛔 system system		
		Receipt Log	ACTINE	Document	Protocol	Log to be checked off an	10 Sep 2021	🛔 system system		
		Cover Letter	ACTIME	Communication	Letter	Letter included in shipme	10 Sep 2021	🛔 system system		
		Patient Brochure	ACTIVE	Document	Protocol	Initial protocol patient br	10 Sep 2021	🛔 system system		
		Marketing Introducti	ACTIME	Communication	Email	Letter to sites introducing	10 Sep 2021	🛔 system system		
		Interest Questionaire	ACIME	Communication	Fax	Initial study interest	10 Sep 2021	🛔 system system		
		Destruction supplies	ACTIVE	Communication	Letter	Letter set to site with des	10 Sep 2021	🛔 system system		
		Empty ISF Binders	ACTIVE	Document	Protocol	Empty binders for the ho	10 Sep 2021	👗 system system		
		Submission	ACTIVE	Document	Protocol	Submission document of	10 Sep 2021	🋔 system system		

9.5 Inactivating Domain Activity Records

- 1. Click on the **Activities Library** link in the Navigation menu in the panel at the left side of the screen.
 - a. This opens the "Activities Library" window.
- 2. Navigate to the activity name you want to set as Inactive and click the check box before the activity name or click directly on the activity name.
- 3. Click on the **Set Inactive** button in the top-left of the screen.
- 4. This Inactivates the Activity record.

TI CTMS USER GUIDE v1.2

											<u> </u>
		Activities	s Library								
9	-	O Add	🖊 Edit 👔 Delete	Set Inactive						Q. Search	T
l (2	35 Activities	1 Selected							🗇 Number 2	
Trialint	aractiva	Activity	Name	Status	Туре	Subtype	Description	Modified	Modifier		
Tridinite	eracuve	0 Ø m	MS 1.1 UAT DRY R	ACTIVE	Acknowlegement	IRB/EC	CTMS 1.1 UAT DRY RUN 0	21 Sep 2021	🛔 admin admin	General Information	
		1 🗇 CT	MS 1.1 UAT DRY R	ACTIVE	Acknowlegement	IRB/EC	TEST	21 Sep 2021	👗 admin admin	Activity	
Dashboard Sponsors	3	0 🗑 ct	MS 1.1 UAT DRY R	INACTIVE	Approval	Annual Renewal	test2	21 Sep 2021	🛔 ədmin ədmin	Number 2	
Programs		🗹 🙆 Nu	umber 2	ACTIVE	Approval	Initial	Second Activity Approval	24 Sep 2021	🔒 admin admin		btype
Products		🔲 🛱 Nu	umber 1	ACTIVE	Acknowlegement	IRB/EC	Activity Advnowledgment	17 Sep 2021	🛔 ədmin ədmin		hitial
Studies		UA	AT Authoring Activity	ACTIVE	Communication	Letter	Authoring	10 Sep 2021	🛔 admin admin	Description Second Activity Approval	
Organizati	ons	🗆 😂 An	u)	ACTIVE	Document	ICF Template	For Anuj to see how the IL	10 Sep 2021	🛔 system system		
User Mana	agement	Rei	frig Log	INACTIVE	Document	Protocol	Test	10 Sep 2021	🛔 system system		
Activities L	and the second	🗎 😁 Ma	onitoring Schedule	ACTIVE	Meeting	Monitoring Plan	Definition of visit schedul	10 Sep 2021	🛔 admin admin	Associated Plans	
Activity Pla		觉 Zer	ta Team Agenda	PACTIVE	Meeting	TMF Plan	Zeta TMF Plan meetings a	10 Sep 2021	🛔 system system		
		🗇 Gi	nical Monitoring Pl	ACTIVE	Meeting	Monitoring Plan	Workshop to define the P	10 Sep 2021	着 system system		
		Tre	emor Start-up Surv	ACTIVE	Document	Protocol	Initial evaluation of start	10 Sep 2021	🋔 system system		
		Feasib	oility Questionnaire	ACTIVE	Document	Protocol	Site is required to notify t	10 Sep 2021	🛔 system system	1	
		🔲 😥 Fe	asibility Questionn	ACTIVE	Document:	Protocol	initial Study feasibility qu	10 Sep 2021	着 system system		
		Re Re	ceipt Log	ACTIVE	Document	Protocol	Log to be checked off an	10 Sep 2021	🛔 system system	1	
		Co	iver Letter	ACTIVE	Communication	Letter	Letter included in shipme	10 Sep 2021	🛔 system system		
		Pat	tient Brochure	ACTIVE	Document	Protocol	Initial protocol patient br	10 Sep 2021	👗 system system		
		🗍 💭 Ma	arketing Introducti	ACTIVE	Communication	Email	Letter to sites introducing	10 Sep 2021	👗 system system		
		C 🗇 Int	terest Questionaire	ACTIVE	Communication	Fax	Initial study interest	10 Sep 2021	👗 system system		
		De	struction supplies	ACTIVE	Communication	Letter	Letter set to site with des	10 Sep 2021	👗 system system		
		E 🛱 Err	npty ISF Binders	ACTIVE	Document.	Protocol	Empty binders for the ho	10 Sep 2021	👗 system system		
		100 Sul	bmission	ACTIVE	Document	Protocol	Submission document of	10 Sep 2021	a system system		

9.6 Creating Domain Library Activity Plans

- 1. Click on the **Activity Plan Templates** link in the Navigation menu in the panel at the left side of the screen.
 - a. This opens the "Activity Plans Templates" window.
- 2. Click on the **Create Template** in the top-left of the screen.
 - a. This opens the Create Activity Plan Template window.
- Here we need to enter the mandatory metadata to create an activity plan template i.e., Activity Plan Name, Level as indicated by an asterisk (*) symbol next to the field title. Enter any additional information, as necessary.
- 4. If any of the required fields are missing, an error will appear when we click on the **Next Add Activities** button, displaying the fields which need to be filled to create an activity plan template successfully.



	#	Activity Plan Templates		Search	۹,	•
		Create Activity Plan Te	mplate	Step 1 🔹 🖸 🚦	۲.	
	の間に当る目を開た日、	General Information Associated Activities	General Information Centry file Name* Centry Demo Country Gastification Centry Select Centry			Y Fites
۰			Cancel Next Add Activities		l	
T						

- 5. This opens the Associated Activities window.
- Click on the Create button in the associated activities window.
 a. This opens Create Activity window.
- Here we need to enter the mandatory metadata to create an activity for the template i.e., Activity, Type, Sub Type, Description as indicated by an asterisk (*) symbol next to the field title.
- 8. Initially Sub Type is greyed out, once you select a value for the Type from the dropdown menu the related values for the sub type will appear in the dropdown menu.
- 9. If any of the required fields are missing, an error will appear when we click on the **Create** button, displaying the fields which need to be filled to create an activity successfully.
- 10. **(Optional)** Click **Create** or **Create and Add Another** depending on whether you intend to create another activity right away.

Note: The activity records created in this location will be records within the Activities Library, available for future selection.



	#	Activity Plan Templates						Search Q	(AA) -
		Create Activity Plan To						Step 2 💿 🖷 🗙	
		General Information Associated Activities	Associated Activities						▼ Filters
								Browse Activities Library	
			Create S3 Remove						
	æ		0 Activities	Create Activity	- ×				
			Activity Name			Modified	Modifier		
	a III -			Activity*					
	l			Type* Subtype					
	210 III			V Description*	~				
	С П			Description*					
	5								
				Cancel Create and Add Another Create					
					_				
				Cancel Previous Save Activities					
T		_					_		

- 11. Click on the **Save Activities** button in the create activity plan template window.
 - a. The create activity plan template closes and a template is created.

Note: Activity plans default to Draft status to allow for review and updates before making the plan available for selection by the user community throughout the system.

9.7 Editing Draft Activity plans

- 1. Click on the **Activity Plan Templates** link in the Navigation menu in the panel at the left side of the screen.
 - a. This opens the "Activity Plans Templates" window.
- 2. Navigate to the plan you want to edit.
- 3. Click on the **Edit** button in the top-left of the screen.
 - a. This opens the Edit Activity Plan Template window.
- 4. Make any necessary changes in the Edit Activity Plan Template window.
- 5. Click on **Save Activities** in the bottom of the edit activity plan template window.

TI CTMS USER GUIDE v1.2

	*	Activity Plan Templates									Search Q AA
	«		Activity Plan Tem	nplates							
		Fo	🕜 Create Template 🥒 B	-	Publish Ø Set to Retired	📋 Delete					Q Search Titers
			15 Activity Plan Templates Plan Name	1 Selected Status	Classification	Description	Level	Activities	Parent Plan	Modified Date	Modifier
		TrialInteractive	Demo	Draft			👗 Study	1		24 Sep 2021	🛓 admin admin
			CTMS 1.1 UAT DRY RUN 0	Recired 0	Amendment	CTMS 1.1 UAT DRY RUN 010_TEST	👗 Study	2		21 Sep 2021	🚨 admin admin
	626 []	Deshboerd Sponsors	I Starter	Dreft			A Study	2		17 Sep 2021	🚢 admin admin
	2	Programs	Test Plan 2	Draft			Q Country	2		10 Sep 2021	🚔 admin admin
	<u> </u>	Products Studies	UAT plan	Retired 🕜	Archival		👗 Study			10 Sep 2021	🛔 admin admin
	A B	Organizations	SSU for Peds Site	Published			🛱 Site	1	SSU for Peds C	10 Sep 2021	🛔 system system
	105	Contacts	SSU for Peds Country 1 Related Plan	Published			Q Country	1	SSU for Peds	10 Sep 2021	🚢 system system
		User Management Activities Library	SSU for Peds 2 Related Plans	Published	Start-up	SSU Pediatric	A Study	2		10 Sep 2021	💄 system system
	_	Activity Plan Templates	Test Plan	Draft			Q Country	1		10 Sep 2021	🚢 system system
	0	Milestone Templates	Status test plan	Retired			A Study			10 Sep 2021	🛔 system system
			Site Close-out	Retired 🕜	Close-out		🛱 Site			10 Sep 2021	📥 system system
			🖪 Investigator Meeting	Retired	2						
			Site Start-up Plan	Published	Start-up	Initial Site EC start-up	🛱 Site	2	Country Study	10 Sep 2021	💄 system system
			Country Study Start-Up 1 Related Plan	Published	Start-up	Country EC start-up	Q Country	2		10 Sep 2021	💄 system system
			Study Start-Up	Published	Start-up		A Study	2		10 Sep 2021	💄 system system
٠											
F											

9.8 Publishing Activity Plans

- 1. Click on the **Activity Plan Templates** link in the Navigation menu in the panel at the left side of the screen.
 - a. This opens the "Activity Plan Templates" window.
- 2. Navigate to the plan name which is in **Draft** status you want to publish it and click on it.
- 3. Click on the **Publish** button in the top-left of the screen.
- 4. Activity plan is displayed with a status of published and can no longer be updated.

TI CTMS USER GUIDE v1.2

* ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	Activity Plan Ter	nplates							
$\mathbf{Y}_{\mathbf{z}}$	🔿 Create Template 🧳 🧪	Edit 🗋 Copy 🔮	Publish Ø Set to Retired	1 Delete					Q Search T Ri
\mathcal{O}	14 Activity Plan Templat	1 Selected							
TrialInteractive	Plan Name	Status	Classification	Description	Level	Activities	Parent Plan	Modified Date	Modifier
	CTMS 1.1 UAT DRY RUN	3' Resired 🕜	Amendment	CTMS 1.1 UAT DRY RUN 010_TEST	A Study			21 Sep 2021	📥 admin admin
Dashboard	Starter	Draft	_		A Study	2		17 Sep 2021	🚨 ədmin ədmin
Sponsors	Test Plan 2	Draft			🐑 Country	2		10 Sep 2021	🐣 admin admin
Programs Products	UAT plan	Reinel @							
A Studies	SSU for Peds Site	Published			🛱 Site	1	SSU for Peds C	10 Sep 2021	🛔 system system
Organizations	SSU for Peds Country 1 Related Plan	Published			Country	1	SSU for Peds	10 Sep 2021	💄 system system
Contacts User Management	SSU for Peds 2 Related Plans	Published	Start-up	SSU Pediatric	A Study	2		10 Sep 2021	🚨 system system
Activities Library	Test Plan	Draft			Q Country	1		10 Sep 2021	💄 system system
Activity Plan Templates	🛄 Status test plan	Resired			<u>A</u> Study			10 Sep 2021	🛔 system system
Milestone Templates	Site Close-out	Radirad	Close-out		🛱 Site			10 Sep 2021	💄 system system
	Investigator Meeting	Retired	2	Study Start-up Investigator meeting activities	A Study			10 Sep 2021	🚨 system system
	🛄 Site Start-up Plan	Published	Start-up	Initial Site EC start-up	Site	2	Country Study	10 Sep 2021	👗 system system
	Country Study Start-Up 1 Related Plan	Published	Start-up	Country EC start-up	Q Country	2		10 Sep 2021	🚨 system system
	Study Start-Up	Published	Start-up		A Study	2		10 Sep 2021	a system system

9.9 Retiring Activity Plans

- 1. Click on the **Activity Plan Templates** link in the Navigation menu in the panel at the left side of the screen.
 - a. This opens the **Activity Plan Templates** window.
- 2. Navigate to the plan name which is in **Published** status you want to retire and click on it.
- 3. Click on the Set to Retired button in the top-left of the screen.
 - a. Confirmation window for activity plan retirement is displayed.
- 4. Enter a reason for retiring the activity plan.
- 5. Click on the **Set to Retired** button in the window.



TI CTMS USER GUIDE v1.2

	*	Activity Plan Templates										AA •
	×	E	Activity Plan Ter Create Template 14 Activity Plan Template Plan Name	View [] Copy		E Delete	Level	Activities	Parent Plan	Modified Date	Q, Search Modifier	¥ Filters
		TrialInteractive	CTMS 1.1 UAT DRY RUN	0' Recired 🕜	Set to Retired		- x				🚨 admin admin	
	R	Dashboard	Starter	Draft	Sectored			2		17 Sep 2021	🚨 admin admin	
		Sponsors	Test Plan 2	Draft	Do you want to set the followin	g Activity Plan Template to Retired?		2		10 Sep 2021	🛔 admin admin	
	2		🛄 UAT plan	Reired 🕜				2		10 Sep 2021	🛔 admin admin	
			SSU for Peds Site	Published	Template Name SS			1	SSU for Peds C	10 Sep 2021	💄 system system	
		Organizations	SSU for Peds Country 1 Related Plan	Published	Classification				SSU for Peds	10 Sep 2021	💄 system system	
		Contacts User Management	SSU for Peds 2 Related Plans	Published	Associated Activities 1			2		10 Sep 2021	💄 system system	
		Activities Library	Test Plan	Draft	Description Parent Plan Name SS	I fax Davis Causer		1		10 Sep 2021	💄 system system	
		Activity Plan Templates Milestone Templates	Status test plan	Refred	Parent Plan Name 33	o tor reas country					🛔 system system	
			Site Close-out	Recired @	Reason						🛔 system system	
			Investigator Meeting	Retired							🛔 system system	_
			Country Study Start-Up	Published				2	Country Study	10 Sep 2021	System system	
			Study Start-Up	Published				2		10 Sep 2021	System system System system	
					_	Cancel Set to Retired		£			2 75000 275000	
=												
۰												
C												

9.10 Copying Activity Plans

- 1. Click on the **Activity Plan Templates** link in the Navigation menu in the panel at the left side of the screen.
 - a. This opens the "Activity Plan Templates" window.
- 2. Navigate to the plan you want to copy and click on it.
- 3. Click on the **Copy** button in the top-left of the screen.
 - a. This opens the **Copy Activity Plan Template** window.
- 4. Update the necessary fields and click on Next Add Activities.
 - a. This displays all the associated activities.
- 5. Click Browse All Activities in the Copy Activity Plan Template window.
- 6. Select an existing library activity for association to the activity plan.
- 7. Click Save Activities in the Copy Activity Plan Template window.

Note: Draft and Retired activities are not available for selection for any entity.



	#	Activity Plan Templates						Search Q,	A -
		Copy Activity Plan Tem	plate					Step 2 💿 🖷 🗙	
		General Information Associated Activities 2	Associated Activities Q. Search Library / Quick Select					Browse Acovides Library	▼ Filters
			Create S3 Remove						
	æ		2 Activities Activity Name	Туре	f have	Description	Modified	Modifier	
	1		EC Submission	Document	Subtype Protocol	Initial EC Submission	10 Sep 2021	System System	
	1		IRB Submission	Document	Protocol	Close-out notification to EC.	10 Sep 2021	System System	
•					Cancel Previous Save Activities	3			
T						_			

9.11 Associating Activity Plan Templates to a Study

- 1. Click on the **Studies** link in the Navigation menu in the panel at the left side of the screen.
 - a. This open the "Studies" window and the studies list is displayed.
- 2. Navigate to the study you want to associate to an activity plan template and click on it.
 - a. This opens the dashboard for the study.
- 3. Click on the Activity Plans link in Navigation menu at the left side of the screen.
 - a. This opens the "Activity Plan" window's Plans in Use section.
- 4. Click on **Templates** in the top-left of the screen.
 - a. This opens the "Templates" window and templates list is displayed.
- 5. Click on the **Add** button in the top-left of the screen.
- 6. Now click on the **Associate** from the dropdown menu.
- 7. This opens the Associate Activity Plan Templates to study window.
- 8. Click on the check box before the plan name you want to associate to a study.
- 9. Click on the Associate button in the bottom of the Associate Activity Plan Template window.

Note: Activity plans default to Draft status to allow for review and updates before making the plan available for selection by the user community throughout the system.

This document is proprietary and is protected by U.S. and international copyright laws and trade secret laws. Copyright © 2021 TransPerfect International, Inc. (TransPerfect). All rights reserved. No part of this document may be reproduced, copied, adapted, modified, distributed, transferred, translated, disclosed, displayed or otherwise used by anyone in any form or by any means without the express written authorization of TransPerfect Senior Management and/or Product Management. Other names may be trademarks of their respective owners.



	*	Ä Study Diagnova ▼ Activity Pla	ans Templates	Search Q, AA -
	*		Activity Plans	
		Diagnova	Plans In Use Scheduled Plans Templates	Q Search ▼ Filters
	89 ♀ 39 🖄 :: 📰 🗃 🕆	Study Details Dashboard Milestones Subgest Subjests Contacts Contacts Team Activities Activities	No records available	
٠				
C				

9.12 Scheduling Activity Plans

- 1. Click on the **Studies** link in the Navigation menu in the panel at the left side of the screen.
 - a. This open the studies window and studies list is displayed.
- 2. Click on the name of the study to which you want to associate an activity plan template.
 - a. This opens the **dashboard** for the study.
- 3. Click on the Activity Plans link in Navigation menu at the left side of the screen.
 - a. This opens the Activity Plan window's Plans in Use section.
- 4. Click on the **scheduled Plans** button in the activity plans screen.
 - a. This opens the Scheduled Plan window.
- 5. Click on the **Add** button in the top-left of the screen.
 - a. This opens the "Scheduled Activity Plan for Study: "Study Name" Sites" window.
- 6. Navigate to the activity Plan you want to schedule, click on it.

TI CTMS USER GUIDE v1.2

	중 Study Diagnova -	Activity Plans Schedul	ied Plans		Search Q 📣 🗸
	● д	Activity			
	i Study Details Beshboard ♀ Milestones ● Countries	Plans In U Add I Scheduled	Select Template	Press select Template from the list that you want to schedule for Study "Diagnow" Sites Level All v Classification All v Q Search 3 Available Templates 1 Selected Site Site	I • 0 0 □ X Q_Search
	 Stess Subjects Organizations Contacts Team Activities Activities 	admin adm		Accer Not Applied Country Active Not Applied SSU for Peds Country	1 Activities • Ischedule plan 1 Activities
				Active SSU for Peds Site	✓ Schedule plan 1 Activities
				Cancel Next	
* G					

- Now click on the Next button in the bottom on the window.
 a. This opens the "Schedule Plan" tab on the window.
- 8. Select at least one level of status by clicking on the dropdown.
 - a. Select one value from the dropdown.
- 9. Click on **Schedule** button on the bottom of the window.

TI CTMS USER GUIDE v1.2

ш	*	Activity Plan	ns Schedul	ed Plans		Search Q. 📣 🗸
	×		Activity	Plans		
		Diagnova	Plans In U	Schedule Activity Plan Select Template	n for Study: "Diagnova" Countries Step 3 • • • • • •	Q Search T Filters
	88 ♀ ◎ 意 10 10 10 10 10 10 10 10 10 10 10 10 10	Sudy Details Dashboard Miessones Courries Sies Subjects Contracts Contracts Team Activities Activities	1 Scheduled	Plan Details Schedule Plan	The Activity Man will be applied to the Study: "Diagnova" Countries when the selected statuses are reached for each lived selected	Sert By Linkneen • • • • • • • • • • • • • • • • • •
=					Cancel Previous Schedule	
* E						

- 10. If you want to cancel the scheduled plans which was scheduled.
- 11. Navigate to scheduled plans window and click on the scheduled activity plan you want to cancel.
- 12. Click on the **Cancel Schedule** button in the top-left of the screen.

	*	Ä Study Diagnova ▼	Activity Plans	Scheduled Plans	Search Q AA -
	•		A	Activity Plans	
			Р	Plans In Use Scheduled Plans Templates	
		Diagnova		S Add / Edit O Cancel Schedule	Q Search Tilters
			1	Scheduled Plans 1 Selected	Sort By Unknown 🗸
	æ	Study Details Dashboard		Country	🛩 0 Countries Applied
	9 0	Milestones		Control O 24 Sep 2012, SS00 PM admin admin	Country 1
	i i	Sites Subjects			
	(변 (영)	Organizations Contacts			
		Team Activities			
		Activity Plans			
٠					
T					



9.13 Tracking Activities Outside of Activity plans

- 1. Click on the **Studies** link in the Navigation menu in the panel at the left side of the screen.
- a. This open the "Studies" window and studies list is displayed.2. Click on the name of the study for which you need to check the activities.
 - a. This opens the dashboard for the study.
- 3. Click on the Activities link in the Navigation menu at the left side of the screen.
 - a. This opens the "Activities" screen.
- 4. Click on the **Add** button in the top-left of the screen.
 - a. This opens the Create Activity window.
- 5. Here we need to fill the mandatory metadata to create an activity i.e., **Activity Name, Type, Sub Type, Description** as indicated by an asterisk (*) symbol next to the field title.
- 6. Initially Sub Type is greyed out, once you select a value for the Type from the dropdown menu the related values for the sub type will appear in the dropdown menu.
- 7. If any of the required fields are missing, an error will appear when we click on the **Create** button, displaying the fields which need to be filled to create an activity successfully.
- 8. **(Optional)** Click **Create** or **Create and Add Another** depending on whether you intend to create another activity right away.

	*	∆ Study Diagnova ▼									Search	Q	•
	•		Activities										
				anned Past Due	Closed								
		Diagnova	🖸 Add 🥒 Edit 👔	ff Delete							Q Sea		T Filters
			1 Activities 1 Selected								🗇 Site Meeting		1
			Activity Name	Status	Туре	Subtype	Description	Owner	Planned Date	Associated Plan	Open		
		Study Details Dashboard	Site Meeting	Open	Create Activ	/ity			• ×		General Information		•
		Milestones									Activity Name		
	0 (1)	Countries Sites			Activity Name*				_		Site Meeting		
		Subjects			Type*		Subtype				Туре	Subtype	
		Organizations			Type		✓		~		Meeting	Investigator Mee	eting
		Contacts			Description*						Description Site investigator meeti	ng	
	₿	Team Activities											
		Activity Plans							_		Associated Plan		
											Applied Date	Applied By	
						_		_			m		
						Cancel	and Add Another Cre	eate			Activity Management		
									_				
											Status Status Open		Status
											Status Notes		
=													
٠													
$\overline{}$												🕲 Status H	listory
C											Owner*		

- 9. To edit any activity, select the activity name and click on the **Edit** button in the top-left of the screen.
- 10. This opens the quick-view window on the right side of the screen, make necessary changes in the activity.
- 11. Click on the Save button in the bottom right of the screen.

This document is proprietary and is protected by U.S. and international copyright laws and trade secret laws. Copyright © 2021 TransPerfect International, Inc. (TransPerfect). All rights reserved. No part of this document may be reproduced, copied, adapted, modified, distributed, transferred, translated, disclosed, displayed or otherwise used by anyone in any form or by any means without the express written authorization of TransPerfect Senior Management and/or Product Management. Other names may be trademarks of their respective owners.



	*	∆ Study Diagnova ▼ Activities									Search Q. A •
	*		Activities								
			All Open Unpla	anned Past Due	e Closed						
		Diagnova		Delete							Q, Search TRitters
			1 Activities 1 Selected								🗑 Site Meeting
			Activity Name	Status	Type	Subtype	Description	Owner	Planned Date	Associated Plan	Cpen
		Study Details	Site Meeting	Open	Meeting	Investigator Meeting	Site investigator m	🐣 Admin Admin			General Information
	62b 0	Dashboard Milestones									
	0	Countries									Activity Name* Site Meeting
	۵	Sites									Type* Subtype*
		Subjects Organizations									Meeting V Investigator Meetin V
		Contacts									Description*
		Team									Site investigator meeting
		Activities									
		Activity Plans									Associated Plan*
											•
											Applied Date Applied By
											m .
											Activity Management
											Status Status Date Open
											Status Notes
٠											
T											Cancel Save & Next >

9.14 Tracking Actions Taken Toward Activity Completion

Some activities associated with studies or sites, especially records of deviations associated with site visits, may require correction or additional steps associated with their eventual completion. Users may enter these actions in the right-side menu. See the screenshot below:

Ac	tivitie	s									
All • A	Open	Unplanned Edit 📋 Delete	Past Du		sed						Q Search Y Filters
4 Act	tivities 1 S Activi	elected Status	Туре	Subty	Descr	Owner	Resp	Planned Date	Assoc	Unbli	Study Investigator Meeting
	₩		Sub App	Initial Initial	Initi Initi	AA			🛄 S	No No	Actions Taken
	₩	IN PROGRESS	Mee Doc	Inve Prot	Inve Initi	▲ A			SS	No No	Add Action Ald Action
											Invitations sent 26 May 2022 Meeting scheduled for 12 June 2022

10 Milestones

10.1 Pre-Requisites

Any users who are responsible for creating and managing **Milestones** must have been granted appropriate access rights by the Company Administrator.

10.2 Creating Domain Library Milestone Template

- 1. Navigate to the Home Screen by clicking on the home icon in the top-left of the screen.
- 2. Click on the **Milestone Templates** link in the Navigation menu in the panel at the left side of the screen.
 - a. This opens the "Milestone Templates" window.
- 3. Click the **Create** button in the top-left of the screen.
 - a. This opens the "Create Milestone Template" window.
- Here we need to enter the mandatory metadata to create a milestone template i.e., Level, Template Name as indicated by an asterisk (*) symbol next to the field title. Enter any additional information as necessary.
- 5. If any of the required fields are missing, an error will appear when we click on the **Create** button displaying the fields which need to be filled to create a milestone template successfully.

	*	Milestone Templates					Search Q 🗛 🗸
	K	7	Milestone Temp Create	plates 🖹 Delete 🛛 Set to Retired 🔷 Publish 🔯 Copy			Q Search Y Filters
		\bigcirc	Create Milesto	one Template		Step 1 🔹 🗖 🗙	Sort By Unknown ~
		TrialInteractive	General Information	General Information			🛱 Site
	80 1	Dashboard Sponsors		· · · · · · · · · · · · · · · · · · ·			
	2	Programs Products		Template Name*	Classification Select		🛱 Site Updated 23 Sep 2021 admin admin
	山田田田田田田田田田田田田田田田田田田田田田田田田田田田田田田田田田田田田田田	Studies Organizations Contacts		Description			Country
		User Management Activities Library					Updated 23 Sep 2021 admin admin
		Activity Plan Templates Milestone Templates					👗 Study
							Updated 23 Sep 2021 admin admin
							👗 Study Updated 10 Sep 2021 admin admin
							🛱 Site
							Updated 01 Sep 2021 admin admin
			Manual	Cencel	Create		Lipdated 31 Aug 2021 admin admin
•			Retired	Amendment			Study
7				♥ test			Updated 10 Sep 2021 admin admin
*				Amendment 9 test			∆ s

6. The **Create Milestone Template** window will close, and milestone template will be displayed.

10.3 Creating a Study Milestone from a Template

- 1. Click on the **Studies** link in the Navigation menu in the panel at the left side of the screen.
 - a. This opens the "Studies" window, and study list is displayed.
- 2. Click on the name of the study for which you want to create a milestone.
 - a. This opens the study.

T R I A L INTERACTIVE

- Click on the Study Details link in the Navigation menu at the left side of the screen.
 a. This opens the "Study Details" window.
- 4. Click on the **Settings** button in the top-right of the screen.

	*	≪ ••• A Study Diagnova ▼ S	tudy Details	Search Q.	AA -
	×		Diagnova II A Þuga F Eft V Stpand Al		Plenned
		Diagnova		• Security	85
			General Information		•
		Study Details Dashboard	Protocol Number Name 00123 Diagnova	Program	
	•	Milestones	Sponsor	Products 1 Product	- 1
	0 1	Countries Sites	A+ Drugs	Diagnova PRIMARY	
	Ł	Subjects	Virtual Study 💿 🚯		
	() 영상	Organizations Contacts			_
	+ 3	Team Activities	Protocol Information		•
		Activity Plans	Protocol Title	Phase	
			Diagnova 321	I Types 0 Types	
			Protocol Summary		
				Mechanisms 0 Mechanisms	_
			Therapeutic Areas 0 Therapeutic Areas	Objectives 0 Objectives	
=				openie o openie	
٠			Indications 0 Indications		
T				Designs 1 Designs	
6					

- Click on the Milestone Templates link in the Navigation menu at the left side of the screen.
 a. This opens the "Milestone Template" window.
- 6. Click on the **Add** button in the top-left of the screen.
- 7. Click on **Add from Sponsor** in the drop-down menu.
 - a. This opens the "Add Milestone Template from Sponsor" window. A list of all the available milestone templates is displayed, select one if you have the milestone template you are looking for.



	A Study Diagnova ▼	Study Settings Milestone Templates	Search Q	AA) -
	• π	Milestone Templates		
	\mathbf{A}	Add → Ø Start Tracking P Edit B Delete Ø Set to Resired Φ Publish Copy La Add From Sponsor		Filters
	Diagnova	O Create New	Sort By Unknown ~	I
		No records available		
	 General Regions 			
	Milestone Templates	3		
٠				
T				

8. Click on the Add button in the Add Milestone Template from Sponsor window.

	K ■ Study Diagnova ▼ Study S	Settings Milestone Templates				Sear	rch Q	•
4	 Add Milestone Templ 	late From Sponsor					× =	
	Telected Milestones 0					Q Sea	rch	T Filters
	Sponsor Milestones	Level All ~ Classification All ~						
		5 Milestones Templates						
		Milestone	Level	Description	Туре	Classification		
	4	First Subject Enrolled	Study	This milestone will be achieved when the				
	1	Initial Ethics Approval (IRB/IEC)	Site		Manual	Regulatory		
		PSSV	Site		Manual			
			Site		Manual			
		COV.	2/16		manuar			
•			Cancel	Add				
_								
E								



10.4 Editing Domain Milestone Templates

- 1. Navigate to the Home Screen by clicking on the home icon in the top-left of the screen.
- 2. Click on the **Milestone Templates** link in the Navigation menu at the left side of the screen.
 - a. This opens the "Milestone Templates" window.
- 3. Click on the milestone template you want to edit.
- 4. Click on the Edit button in the top-left of the screen.a. This opens the "Edit Milestone Template" window.
- 5. Make any necessary changes.
- 6. Click the **Save** button.
- 7. The Milestone Template is **Updated** and displayed in the list

Note: You can edit only milestone templates with Draft status.

		Milestone Templates					Search Q A
	•	\sim	Vilestone Temple O Create	ates			Q. Search Titers
		6	Edit Milestone			Step 1 🔹 🗖 🗙	Sort By Unknown ~
		TrialInteractive	General Information	General Information			🛱 Site
		Deshboard Sponsors Programs Studies Organizations Contacts User Management Activities Library Activities Library Activities Library Microson Trimplanes		Level* Site Trongians Name* Third - Copy (Milestone UAT) Description	Countries Cassification Select		Updared 23 Sep 2021 admin admin See Updared 23 Sep 2021 admin admin Country Updared 23 Sep 2021 admin admin Lipotared 23 Sep 2021 admin admin Lipotared 23 Sep 2021 admin admin Lipotared 23 Sep 2021 admin admin
							Updated 10 Sep 2021 admin admin
				Cancel	Save		Updated 01 Sep 2021 admin admin
			Manual	,			Updated 31 Aug 2021 admin admin
* T				mendment ₽ test			Lipidated 10 Sep 2021 admin admin

10.5 Deleting Domain Milestone Templates

- 1. Navigate to the Home Screen by clicking on the **home** icon in the top-left of the screen.
- 2. Click on the **Milestone Templates** link in the Navigation menu in the panel at the left side of the screen.
 - a. This opens the "Milestone Templates" window.
- 3. Click on the milestone template which needs to be deleted.
 - a. Please note that the template needs to be in Draft status to be deleted.

This document is proprietary and is protected by U.S. and international copyright laws and trade secret laws. Copyright © 2021 TransPerfect International, Inc. (TransPerfect). All rights reserved. No part of this document may be reproduced, copied, adapted, modified, distributed, transferred, translated, disclosed, displayed or otherwise used by anyone in any form or by any means without the express written authorization of TransPerfect Senior Management and/or Product Management. Other names may be trademarks of their respective owners.



- 4. Click on the **Delete** button in the top-left of the screen.
 - a. This opens the "Confirmation" window.
- 5. Click on the **Delete** button in the confirmation page.
- 6. The Milestone Template will be **Deleted** from the list.

	*	Milestone Templates					Search Q. 🔕 🗸
	۲	E	Milestone Ten O Create I Edit 15 Milestones 1 Selecto	Delete @ Set to Retired	♦ Publish 10 Copy		C, Seech T Filters Sert By Unknown ~ E E
	63	TrialInteractive Deshboard	Manual	• Third - Copy (Milestor	ne UAT)		🛱 Sre Updated 23 Sep 2021 admin admin
		Programs	Published	9 Third			🛱 Ste Updated 23 Sep 2021 admin admin
	間留留		Published	9 Second	Confirmation Do you want to delete the sele	cted Milestone Template?	Country Updated 23 Sep 2021 admin admin
		Activity Plan Templates Milestone Templates	Public Manual	9 First	Cancel	Delete	👗 Study Updated 23 Sep 2021 admin admin
			Dott) Manual	Amendment 9 test - Copy			👗 Soudy Updased 10 Sep 2021 admin admin
			Published Manual	Regulatory 9 Initial Ethics Approva	al (IRB/IEC)		Soe Updated 01 Sep 2021 admin admin
=			PLOIDed Manual	^{Close-out} 9 Anuj Milestone			👗 Study Updated 31 Aug 2021 admin admin
* C			Resid	Amendment 9 test			ل Study Upstaned 10 Sep 2021 admin admin

10.6 Publishing Milestone Templates

- 1. Navigate to the Home Screen by clicking on the **home** icon in the top-left of the screen.
- 2. Click on the **Milestone Templates** link in the Navigation menu in the panel at the left side of the screen.
 - a. This opens the "Milestone Templates" window.
- 3. Select the **Draft** template you want to publish.
- 4. Click on the **Publish** button in the top-left of the screen.
 - a. This opens the "Please Review Milestone Template" window.
- 5. Click on the **Publish Milestone Template** button in the **Please Review Milestone Template** window.
- 6. Milestone Template is **Published** and displayed in published status on the list.

Note: Milestone Templates are not available for selection by the user community until **Published**.

This document is proprietary and is protected by U.S. and international copyright laws and trade secret laws. Copyright © 2021 TransPerfect International, Inc. (TransPerfect). All rights reserved. No part of this document may be reproduced, copied, adapted, modified, distributed, transferred, translated, disclosed, displayed or otherwise used by anyone in any form or by any means without the express written authorization of TransPerfect Senior Management and/or Product Management. Other names may be trademarks of their respective owners.

TI CTMS USER GUIDE v1.2

	Milestone Templates		Search Q 🗛 -
	Trainteractive	Milestone Templates Create Create Set to Retard Create Set to Retard Create TS Milestones 1 Selected Final P Third - Copy (Milestone UAT)	Q Snerh ▼ Fiters Sert By Unknown ✓ ■ ■ © Ste Updated 23 Sep 2021 admin admin
	Deshboard Sponsors Programs Products	Please Review Milestone Template	🛱 Site Updated 23 Sep 2021 admin admin
	Studies Organizations Contacts User Management	Construction C	Country Updaced 23 Sep 2021 admin admin
	Activities Library Activity Plan Templates Milestone Templates	P First Classification Manual Type Manual	Lipdated 23 Sep 2021 admin admin
		Remember Ammendment Ø test - Copy Cancel Publish Misstore Templete	∐ Study Updated 10 Sep 2021 admin admin
		Marual Regulatory • Initial Ethics Approval (IRB/IEC)	😰 Site Updated 01 Sep 2021 admin admin
=		Marual Class-out 9 Anuj Milestone	Lpdsted 31 Aug 2021 admin admin
* E		Maruel Amendment V test	∐ Study Updated 10 Sep 2021 admin admin

10.7 Retiring Milestone Templates

- 1. Navigate to the Home Screen by clicking on the **home** icon in the top-left of the screen.
- 2. Click on the **Milestone Templates** link in the Navigation menu in the panel at the left side of the screen.
 - a. This opens the "Milestone Templates" window.
- 3. Navigate to the milestone template you want to retire and click on it.
- 4. Click on the **Set to Retired** button in the top-left of the screen.
 - a. This opens the "Set to Retired" window.
- 5. Click on the **Set to Retired** button in the "Set to Retired" window.
- 6. Milestone Template is **Retired** and displayed in the list

Note: Only Published templates can be Retired.

TI CTMS USER GUIDE v1.2

	Milestone Templates		Search Q 🗛 🗸
		Milestone Templates Crear Cre	Geneth Fiter Geneth Fiter Geneth Genet
	User Management Activities Library Activities Library Activity Plan Templates Microone Templates	First Pirst Manual Pirst Manual Pirst Manual Pirst	Lipitand 23 Sep 2021 admin admin Lipitand 23 Sep 2021 admin admin Lipitand 10 Sep 2021 admin admin
		Regulatory Cancel Set to Reserved Manual P Initial Ethics App Cancel Set to Reserved Concel Cancel Set to Reserved Set to Reserved Manual P Anuj Milestone Set to Reserved Set to Reserved	Updated 11 Sep 2021 admin admin Ste Updated 01 Sep 2021 admin admin Study Updated 31 Aug 2021 admin admin
•		Amendment Menuel Amendment	Updated 31 Aug 3021 admin admin Study Updated 10 Sep 3021 admin admin

10.8 Copying Milestone Templates

- 1. Navigate to the Home Screen by clicking on the **home** icon in the top-left of the screen.
- 2. Click on the **Milestone Templates** link in the Navigation menu in the panel at the left side of the screen.
 - a. This opens the "Milestone Templates" window.
- 3. Navigate to the milestone template you want to copy and click on it.
- 4. Click on the **Copy** button in the top-left of the screen.
 - a. This opens the "Copy Milestone Template" window.
- 5. Click on the Copy button in the Copy Milestone Template window.
- 6. Milestone Template is Copied, and the copy is displayed in the list

TI CTMS USER GUIDE v1.2

	#	Milestone Templates					Search Q AA
	K	Trisilinteractive	Copy Milestone Te	Ø Set to Retired Publish		Step 1 🔹 🗖 🗙	Q Search Y Filters Sert By Unknown - E E
		Deshboard Sparson Programs Products Studies Orgenizations Consect User Management Activities Ukary Activities Ukary Activities Ukary Activities Ukary Mitanter Templates	General Information	General information Lever* Site Tempter: Name* Third-Copy (Milestone UAT) - Copy Description	Countries CashGasion Select		€ Sor Updated 23 Sop 2021 admin admin € Sor Updated 23 Sop 2021 admin admin € Country Updated 23 Sop 2021 admin admin & Soutry Updated 23 Sop 2021 admin admin & Soutry
=			Manual Amenda		Capy		Updated 015ep 2021 admin admin Study Updated 31 Aug 2021 admin admin Study
T			Manual 9 test				Updated 10 Sep 2021 admin admin

10.9 Associating Milestone Templates to a Sponsor

- 1. Navigate to the Home Screen by clicking on the **home** icon in the top-left of the screen.
- 2. Click on the **Sponsors** link in the Navigation menu at the left side of the screen.
 - a. This opens the "Sponsors" window and list of sponsors is displayed.
- 3. Click on the sponsor to which you wish to associate a template.
 - a. This opens the "Sponsor Details" window.
- 4. Click on the **Settings** button in the top-right of the screen.
 - a. This opens the "Sponsors Setting Milestone Template" screen.



		Sponsor		
	*)	Dermeron • Sponsor	Details	Search Q AA -
	«		Dermeron	ktive .
				S Edit History
		Dermeron		© Settings
			Organization Information	-
		Sponsor Details	Number Status Description	
		Programs	0001 Active 0	
	_	Products	Name Dermeron	
	_	Studies Sites	Parent Organization	
		Organizations		
	쓥	Contacts	Type Subtype Notes	
			Sponsor	
			Contact Information	•
			Primary Contact	
			Finally Contact	
			View All Contacts	
			TECH AR CONTROLS	
٠			Addresses	
T			O Add de Edit. III Delete	
6			No records available	

- 5. Click on the **Add** button on the top-left of the screen.
- 6. Click on **Add from Domain** in the dropdown menu.

		Sponsor Dermeron • Sponsor	Settings Milestone Ter	nplates	Search Q 🗛 🗸
	۲		Milestone Ten		
			Add Zedit Add From Domain Create New	🖹 Dolose @ Secto Resired 🗢 Publish 🕲 Capy	Q, Search Y Filters
		Dermeron	Published	Start-up	∆ Study
	Ŷ	Milestone Templates	Manual	Final Protocol	Updated 16 Sep 2021 admin admin
			Published	Regulatory 9 Initial Ethics Approval (IRB/IEC)	貴 Site
			Manual	a second a second a second s	Updated 01 Sep 2021 admin admin
			Domain Manual	9 First Subject Enrolled This milestone will be achieved when the first subject for the study	Lipdated 01 Sep 2021 admin admin
٠					
T					

TI CTMS USER GUIDE v1.2

6	Add Milestone Temp	late Fi	rom Domain						• ×	
	₩ Selected Milestones 0							Q Search		▼ Filters
	Domain Milestones	Level /	Classification All ~							
			Milestone	Level	Description	Туре	Classification			👗 Study
			First Subject Enrolled	Study	This milestone will be achieved when the	Manual				in admin
			Anuj Milestone	Study		Manual	Close-out			
			Initial Ethics Approval (IRB/IEC)	Site		Manual	Regulatory			Site
			First	Study		Manual				n admin
			Second	Country		Manual				
			Third	Site		Manual				A Study
				Car	ncel Add					

- 7. This opens the Add Milestone Template from Domain window.
- 8. Select one of the milestone templates from the list and click on the **Add** button.
- 9. The Milestone Template is added to the list.

10.10 Defining Sponsor-Specific Milestone Templates

- 1. Navigate to the Home Screen by clicking on the home icon in the top-left of the screen.
- 2. Click on the **Sponsors** link in the Navigation menu in the panel at the left side of the screen.
 - a. This opens the "Sponsors" window, and the sponsors list is displayed.
- 3. Click on the sponsor that you want to associate with a milestone template.
 - a. This opens the "Sponsor Details" window.
- 4. Click on the Settings button in the top-right of the screen.
 - a. This opens the "Sponsors Setting Milestone Template" screen.
- 5. Click on the **Add** button on the top-left of the screen.
- 6. Click on the **Create New** button from the dropdown.

	B Sponsor	iponsor Settings Milestone Templates	Ssaith Q 🗛 🗸
	•	Milestone Templates	
		O Add	Q Search ▼ Filters
	Dermeron	Start-op	∐ Study
	Milestone Templates	Final Protocol	Updated 16 Sep 2021 admin admin
		Container Regulatory P Initial Ethics Approval (IRB/IEC)	偿 Site
		Manual	Updated 01 Sep 2021 admin admin
		First Subject Enrolled Domain Manual Manual	∑ Study Updated 01 Sep 2021 admin
=			
*			
T			

- 7. This opens the Create Milestone Template window.
- Here we need to fill the mandatory metadata to create milestone template i.e., Level, Template Name as indicated by an asterisk (*) symbol next to the field title. Enter any additional information as necessary.
- 9. If any of the required fields are missing, an error will appear when we click on the **Create** button displaying the fields which need to be filled to create a milestone template successfully.
- 10. Click on the **Create** button in the **Create Milestone Template** window.

This document is proprietary and is protected by U.S. and international copyright laws and trade secret laws. Copyright © 2021 TransPerfect International, Inc. (TransPerfect). All rights reserved. No part of this document may be reproduced, copied, adapted, modified, distributed, transferred, translated, disclosed, displayed or otherwise used by anyone in any form or by any means without the express written authorization of TransPerfect Senior Management and/or Product Management. Other names may be trademarks of their respective owners.



	Sponsor Dermeron Sponsor Set	ttings Milestone Templates				Search Q 🗛 🗸
	•	Milestone Templates				
			Ø Set to Retired ◆ Publish 🖺 Copy		_	Q Search Tilters
	Dermeron	Create Milestone Ter	nplate		Step 1 🔹 🗖 🗙	Sort By Unknown ~ 📰 📰
		General Information	General Information			👗 Study
	Milestone Templates		Ť Š			Updated 16 Sep 2021 admin admin
			Template Name*	Classification Select		🛱 Site
			Description			Updated 01 Sep 2021 admin admin
						👗 Study
						Updated 01 Sep 2021 admin admin
			Cancel	Create		
*						
C						

10.11 Defining Study Milestone Templates (New)

- Click on the Study link in the Navigation menu in the panel at the left side of the screen.
 a. This opens the "Studies" screen.
- 2. Click on the name of the study for which you want to define a new template.
 - a. This opens the study dashboard.
- 3. Click on the Study Details link in the Navigation menu at the left side of the screen.
 - a. This opens the "Study Details" window.
- 4. Click on the **Settings** button in the top-right of the screen.
 - a. This opens the "Study Settings General" window.



		Study Details	Search Q. 📣 🗸
	• 7	Diagnova ∎ Ar Drup	
		✓ Edit	© Edit History
	Diagnova		O Settings
		General Information	•
	i Study Details	Protocol Number Name	Program
	Dashboard Milestones	00123 Diagnova	
	Milestones Countries	Sponsor	Products 1 Product
	Sites	A+ Drugs	Diagnova PRIMARY
	🌡 Subjects	Virtual Study 💭 🚯	
	Organizations		
	 Contacts Team 		
	Activities	Protocol Information	•
	Activity Plans	Protocol Title	Phase
		Diagnova 321	
			Types 0 Types
		Protocol Summary	
		Protocol sommery	
			Mechanisms 0 Mechanisms
		Therapeutic Areas 0 Therapeutic Areas	
		inerapeutic Areas V inerapeutic Areas	Objectives 0 Objectives
٠		Indications 0 Indications	
$\overline{}$			Designs 1 Designs Case-Control
T			

- 5. Click on the Milestone Template link in the Navigation menu at the left side of the screen.
 - a. This opens the "Milestone Template" window.
- 6. Click on the Add button in the top-left of the screen.
- 7. Click on Add from Sponsor from the dropdown.

	*	<	Ä Study Diagnova ▼	Study Settings	Milestone Temp	lates								- 🌑
	×				ne Templat									
				🚑 Add Fro		🥒 Edit	📋 Delete	Ø Set to Retired	Publish	🗈 Сору			Q Search	▼ Filters
	Di	Dia	Diagnova	Create N	ew						No records available		Sort By Unknown ~	
		General												
	N	Regions												
		_												
•														
T														



Note: Clicking Add from Sponsor will allow for the selection of a milestone template that is already associated to your study sponsor.

- 8. Select an available Milestone Template from the list.
- 9. Click on the Add button in the bottom of the Add Milestone Template from Sponsor window.
- 10. The selected sponsor Milestone Templates are displayed in the list

		Settings Milestone Templates				Search	<u> </u>				
	 Add Milestone Temp 	plate From Sponsor					• ×				
	T Selected Milestones 0 Sponsor Milestones	Level All V				Q Search	▼ Filters				
	5 Milestones Templates										
		Milestone	Level	Description	Туре	Classification					
		First Subject Enrolled									
		Initial Ethics Approval (IRB/IEC)	Site		Manual	Regulatory	_				
	4	PSSV	Site		Manual						
		SIV SIV	Site		Manual		_				
		cov	Site		Manual						
•			Cancel	Add							
T							_				
6											

- 11. To create a new Milestone Template, follow these steps.
- 12. Click on the Add button in the top-left of the screen.
- 13. Click on the **Create New** button form the dropdown list.

Note: Clicking Create New will allow for the creation of a new study specific milestone template.



		Study Settings Milestone Templates	Search Q A -
	• π	Milestone Templates	
		Add ← @ Stawt Tradving # Edit Delete Ø Set to Resived Φ Publish Copy Add From Sponsor	Q, Search Titters
	Diagnova	• Create New	Sort By Unknown V
		No records available	
	🔅 General		
	Milestone Templates		
٠			
T			

- 14. Here we need to fill the mandatory metadata to create a milestone template i.e., **Level**, **Template Name** as indicated by an asterisk (*) symbol next to the field title. Enter any additional information as necessary.
- 15. If any of the required fields are missing, an error will appear when we click on the **Create** button displaying the fields which need to be filled to create a milestone template successfully.

		Study Settings Milestone Templates		Search Q	• •
	 π 	Milestone Templates			
		🗘 Add 👻 🐵 Start Tracking 🥒 Edit 🏥 Delete 🐵 Sector Resired 🗢 Publish 🖏 Copy			▼ Filters
	Diagnova		Step 1 • 🗆 🗙	Sort By Unknown ~	
		General Information General Information			
	General	×			
	 Regions ♥ Milestone Templates 	Templan Name* Cassification Stelect			
		Description			
			_		
		Cancel			
۰					
C					



10.12 Tracking Milestones

T R I A L INTERACTIVE

- 1. Navigate to the Milestones you want to track.
- 2. Click on **Start Tracking** in the top-left of the screen.
 - a. This opens the "Start Tracking" window.
- 3. Click on the Yes, start tracking button in the Start Tracking window.

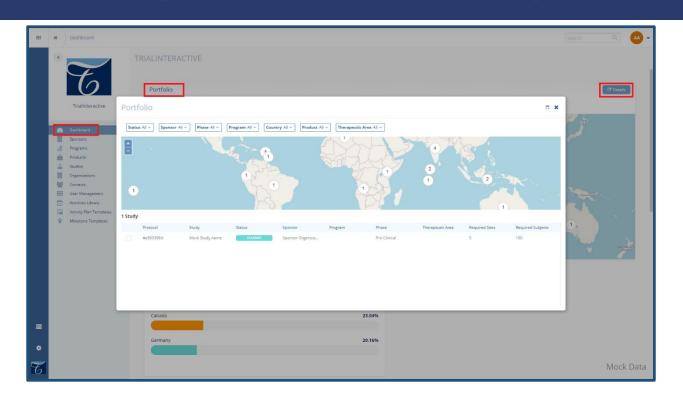
Note: The milestone will not be displayed for tracking at any level until Start Tracking is clicked for the desired milestone.

	*	C and Diagnova +	Study Settings Mile:	stone Templates	Search Q.
	۲		Milestone T	emplates	
				re Tradung 🖍 Edit 📋 Delete 🛛 O Set to Revned 📣 Publish. 🔯 Copy	Q Search Tilters
		Diagnova	1 Milestones		Sort By Unknown 🛩
			Rublished	First Subject Enrolled This milestone will be achieved when the first subject for the study	👗 Study
		General Regions	Manual	This fillestorie will be durier to wrien the his sougest for the source.	Updated 01 Sep 2021 admin admin
		Regions Milestone Templates			
				Start Tracking	
				Do you want to start tracking milestones for the study?	
				Canada Yes, scare translow	
٠					
C					

11 Dashlets

11.1 The Portfolio Dashlet

- 1. Log into the CTMS.
- 2. Click on the **Dashboard** link in the Navigation menu in the panel at the left side of the screen.
- 3. The **Portfolio** dashlet is displayed on the screen.
- 4. Click on the Details button in the top-right of the screen to expand the portfolio window.
- 5. We can use the dropdowns available in the portfolio to restrict our select list to view.



11.2 The Top Countries Dashlet

- 1. Click on the **Dashboard** link in the Navigation menu in the panel at the left side of the screen.
- 2. This displays 3 Top Countries on the screen.
- 3. This list shows the countries with most activities in the system.

	*	Dashboard								Search	۹. 🗛 🔹
	×	TrialInteractive	TRIALINTERACTIVE	10 Agenere		•					menter
		User Management Activities Library Activity Plan Templates	Top Countries	IV.	39.92% 23.04% 20.16%						(F Decals)
•			220 Panned Tasi hars	10 Consent 10 Protocole 11 Concelled 13 Actived 14 Car 14 Car 14 Car 14 Car 15 Consent 25 Consent 25 Consent 25 Onese 25 Enrolling 104 New-Tex	Protocol #111 #222 #333 #444 #555 #666 #777	Study Name Study 1 Study 2 Study 3 Study 4 Study 5 Study 5 Study 6 Study 7	Status PUARED ARCHVRD RUARED ARCHVRD HUARED PUARED	Sponsor Sponsor 1 Sponsor 2 Sponsor 3 Sponsor 4 Sponsor 5 Sponsor 6 Sponsor 7	Program Program 1 Program 2 Program 3 Program 4 Program 5 Program 6 Program 7	# of Planned Sites 1 2 3 4 5 6 7 7 4 Previous	Phanned Subje Phan

11.3 The Studies Dashlet

- 1. Click on the **Dashboard** link in the Navigation menu at the left side of the screen.
- 2. Scroll down to Studies in the dashboard screen.
- 3. This displays the **Studies** information in grid and in pie chart form.
- 4. We can use the Group by dropdown to select a value for grouping.
- 5. Click on the **Details** button to expand the Studies window.



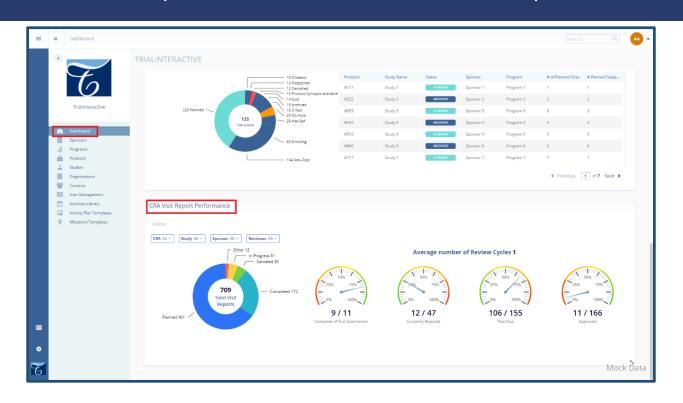
	*	Dashboard									Search	۹ 🗛
	×	TrialInteractive	Germany			20.16%						
		Sponsors Programs Products Studies Orgenizations Contacts User Management Activities Library	Studies Group by Status Status A Spansor Phase Program	Plaze Al - Pregram Al -	10 Closeout 10 Posponed 13 Prototo Synopis Available 14 Curr 14 Curr 25 Chiest 25 Chiest	Protocol #111 #222 #333	Study Name Study 1 Study 2 Study 3	Status FUARED AICHAED FUARED	Spansor Spansor 1 Spansor 2 Spansor 3	Program Program 1 Program 2 Program 3	# of Planned Sites 1 2 3	(* Dessit) (* M) * Panned Subje 1 2 3
	•			125 Teal Studies	29 Wel-Def 65 Enrolling 104 New-Test	#444 #555 #666 #777	Study 4 Study 5 Study 6 Study 7	ARCHIVED FLANNED ARCHIVED FLANNED	Spansar 4 Spansar 5 Spansar 6 Spansar 7	Program 4 Program 5 Program 6 Program 7	4 5 6 7	4 5 6 7
=			CRA Visit Report Perfor Nome CRA All ~ Study All ~	Mance Sponsor All v Reviewer All v]						Previous (1 of 7 Next 🕨
2				Other 12 In Progress 31 Canceled 33				verage number		ycles 1		Mock Dat

11.4 The CRA Visit Report Performance Dashlet

- 1. Click on the **Dashboard** link in the Navigation menu at the left side of the screen.
- 2. Scroll down to CRA Visit Report Performance on the dashboard.
- 3. This displays the data in grid and pie chart format.
- 4. We can use the dropdowns available to filter the search criteria to view.

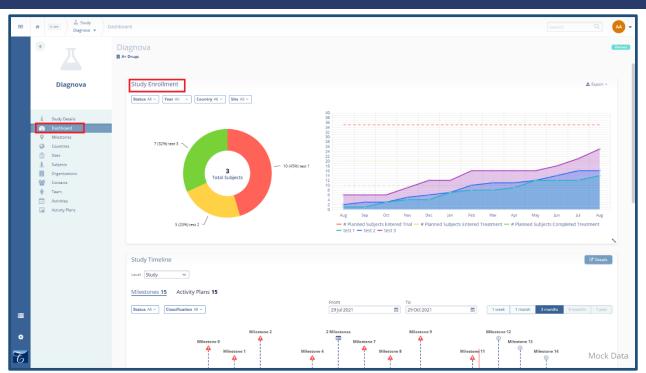


TI CTMS USER GUIDE v1.2

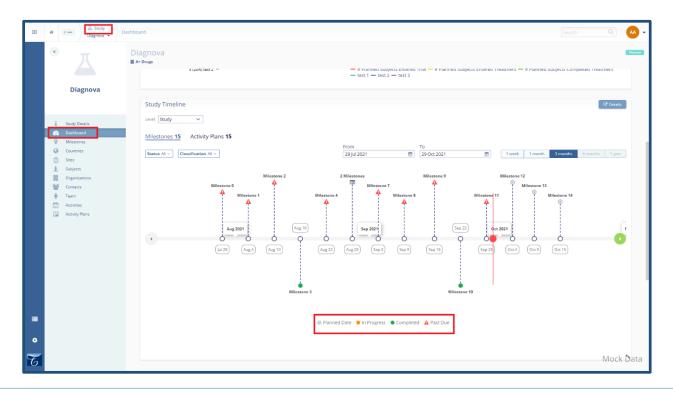


11.5 Reviewing Studies via their Dashboard

- Click on the **Studies** link in the Navigation menu at the left side of the screen.
 a. This opens the "Studies" window.
- 2. Navigate to the study you want to review.
- 3. Study Enrollment, Study Timeline, and Activities dashlets are displayed.
- 4. Navigate to **Study Enrollment** in the dashboard.
 - a. This reflects planned and actual numbers.



- 5. Navigate to the **Study Timeline** in the dashboard.
 - a. This shows a red dot and a line indicating today on the timeline.
- 6. It shows the status of each milestone in the study.



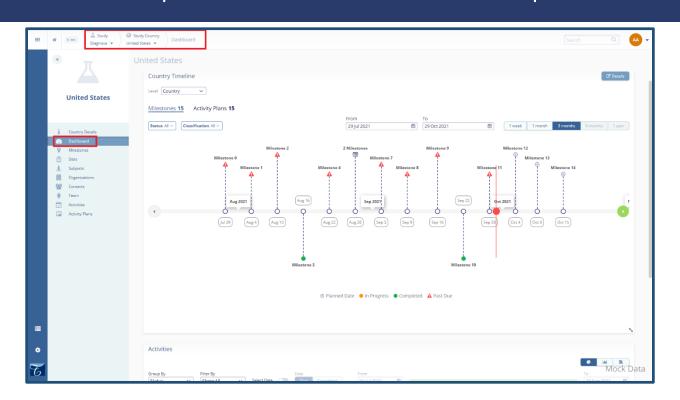


- 7. Navigate to **Activities** on the dashboard.
- 8. This shows data for **Study General Activities**, **Site Total Activities**, **Country Total Activities** in pie chart, that can be changed to a bar graph if preferred.

	*	K *** A Study Diagnova V	Dashboard	Search C	a 🗛 -
	*		Diagnova Il Ar Drugs		Planned
		Diagnova	Milestone 3 Milestone 10		
		Countries	© Planned Date • In Progress • Completed ▲ Past Due Activities		
	* ©	Team	All Activities Group By Status v Select Date Bit Completed Type/Stattype 0 Elters v Owner All v	To 29 Sep 2021	
=			Ist Applicable		
T				M	ock Data

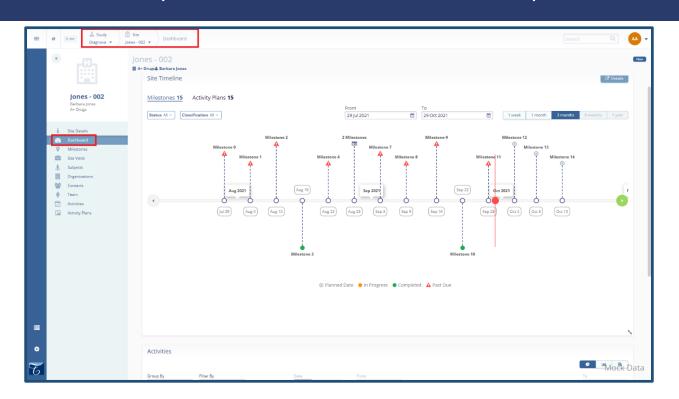
11.6 Reviewing Countries via their Dashboard

- 1. Click on the **Studies** link in the Navigation menu at the left side of the screen.
 - a. This opens the "Studies" window.
- 2. Click on the name of the study you want to review.
 - a. This opens the dashboard for the study.
- Click on the **Counties** link in the Navigation menu at the left side of the screen.
 a. This opens the "Countries" screen.
- 4. Click on the name of the country you want to review.
 - a. This opens the dashboard for the country.
- 5. This displays the **Country Timeline** and **Activities** in the dashboard.



11.7 Reviewing Site Dashboard

- Click on the **Studies** link in the Navigation menu at the left side of the screen.
 a. This opens the "Studies" window.
- 2. Click on the name of the study you want to review.
 - a. This opens the dashboard for the study.
- 3. Click on the Sites link in the Navigation menu at the left side of the screen.
 - a. This opens the "Sites" screen.
- 4. Click on the name of the site you want to review.
 - a. This opens the dashboard for the site.
- 5. This displays the **Site Timeline** and **Activities** in the dashboard.



11.8 Site Visit Report Review Status Dashlet

The Site Visit Report Review Status dashlet is intended to allow users who are indicated as site visit report reviewers to see the status of any reports generated for their studies. Users can filter their view to identify overdue documents along with a number of other available filters.

Users can navigate directly to the Site Visit in question by clicking on the name of the visit as shown in the grid or they can navigate directly to the report to be reviewed by clicking on the "View Report" link in the grid.



ite Visit Re	eport Review	Status							🛓 Export
		No Review	ver 1 Report Status All	✓ Owner All ✓	Reviewer All ~	Study All Y	Site All ~	Visit End Date All ~	
Site Visits Visit Name	Visit End Date	Report Status	Report Statu	Visit Report	Report Due	Owner	Reviewer	Study Name	Site Name
💼 IMV #1	27 May 2022	SUBMITTED	06 Jun 2022	% View Report	1 27 May	CRA 003		DT-001-US	Sunshine
	27 May 2022	Sound	00 jun 2022	• Hen hepoire	0 27 may	childos		51 001 05	Sunshin

12 User and Team Management

12.1 Creating Users

- 1. Click on the **User Management** link in the Navigation menu at the left side of the screen.
 - a. This opens the "User Management" screen.
- 2. Click on the **Invite** button in the top-left of the screen.
 - a. This opens the Invite User window.
- 3. Here we need to enter the required mandatory metadata to create a user i.e., **Email**, **First Name**, **Last Name**, **Global Role** as indicated by an asterisk (*) symbol next to the field title.
- 4. If any of the required fields are missing, an error will appear when we click on the **Invite** button, displaying the fields which need to be filled to invite a user successfully.
- 5. **(Optional)** Click **Invite** or **Invite and Add Another** or **Invite and go to User Profile** depending on whether you intend to create another user right away.

TI CTMS USER GUIDE v1.2

	🗰 🖉 User Ma	anagement				Search Q 🗛 🗸
	• 7		User Management			Q Seech T Files
	Trialin	teractive	Name	Sisturs INVITED	Global Role	Email yogitettifls.com Lunda@s.com
	Dashboar Dashboar Sponsors Programs Products		A yog test CRA DEMO LAT First UAT Last	Invite User	x =	yogrest 23@s.com oredenso@si.com dofourl@gnail.com
	Studies Organizat Contacts User Mar	tions	 Bain Cusack Being Smyth Abhijit Kamble 	Fill in information below to create a u	ser	elan@email.con snytmichael@gmail.com akamble@trangserfect.com
	Activities Activity Pl Milestone	Library Ian Templates	🔹 Suflya Sultana	First Name 4	chime*	sudran@transperfect.com likadysk@transperfect.com kakeson@transperfect.com
			Mr: Owen Omoijuanfo Mr: Susan Geers-Meiners Mrs. Sandesh Visoriya	Cancel Invite and Add another Ir	vite and go to User Profile	oomojuanfo@transperfect.com sgeersmeinen@transperfect.com svisoriya@transperfect.com
			Anncy Drew Appe Weisser Abdul Anwer	ACTAC ACTAC		abdul.anwer@gmail.com howeiser@transperfez.com eanwer@transperfez.com
			👗 John Doe	ACTIVE INACTIVE, INVITED		userT@mail.com test@mail.com
*						
C						

12.2 Editing a User

- Click on the User Management link in the Navigation menu at the left side of the screen.
 a. This opens the User Management screen.
- Navigate to the name of the user you want to edit and click the check box before the username.
 a. This opens the quick view on the right side of the screen.
- 3. Click the **Edit** button on the top-left of the screen or click on the **Pencil Icon** in the quick view panel to make changes in the user account.
- 4. Make any necessary changes to the user account.

TI CTMS USER GUIDE v1.2

🖷 User Management						rdi 🔍 🗛
•	User Management					
F	O Invite Z Edit OD Descrivete	🖬 Edit Permissions 🛛 🖂 Resend Invite			Q	Search T F
(2)	21 Users 1 Selected				test ti	1
	Name	Status	Global Role	Email	TT Ended	
TrialInteractive	🗹 🚨 test ti	(INVITED)		yogitest@ti.com	24 Sep 202	
	🛔 Linda Munn	ENTER O		Linde@ti.com	E Email	
Deshboard	📄 🔺 yog test	ACTIVE		yogtest123@ti.com	General Information	
Programs	👗 CRA DEMO	ACTIVE		crademo@ti.com	Prefix First Name	Middle Name
Products	UAT First UAT Last	ACTIVE		dofourt@gmail.com	test	
👗 Studies	🛔 Elain Cusack	eviteD		elain@email.con	Last Name	Suffix
Organizations	👗 George Smyth	CETING		smytmichael@gmail.com	ti	
User Management	👗 Abhijit Kamble	ACTIVE		akamble@transperfect.com	Global Role	
Activities Library	👗 Sufiya Sultana	ACTINE		ssultana@transperfect.com	None	
Activity Plan Templates	💄 Lakshmi Kadiyala	ACTIVE		lkadiyala@transperfect.com	Status	Type Regular
Milestone Templates	📥 Mr. Kennon Atkeson	ACTIVE		katkeson@transperfect.com	User Since	Created By
	🔒 Mr. Owen Omoijuanfo	ACTIVE		oomoijuanfo@transperfect.com	24 Sep 2021	admin admin
	🌲 Mrs. Susan Geers-Meiners	ACTIVE		sgeersmeiners@transperfect.com	Preferred Languages 0 Lar	guage
	📥 Mrs. Sandesh Visoriya	ACTIVE		svisoriya@transperfect.com		
	👗 Nancy Drew	OTIM		abdul,anwer@gmail.com	Preferred Communication	Method
	👗 Hope Weisser	ACTIVE		howeisser@transperfect.com		
	📥 Abdul Anwer	ACTIVE		aanwer@transperfect.com	Time Zone	Best Contact Time
	👗 John Dae	ACTIVE, INACTIVE, INVITED		userT@mail.com		
	🔄 🛔 John Dae	ACTIVE, INACTIVE, INVITED		test@mail.com	Contact Information	
	🛔 John Test	ACTIVE INACTIVE INVITED		user@mail.com		
	admin admin	ACTIVE		ctms.admin@transperfect.com		cords available
-					Email	
					Primary yogitest@ti.com	×

5. Click on the **Save** button in the bottom right of the screen, for the changes to apply to the user account.

12.3 Editing a User's Permissions

- Click on the User Management link in the Navigation menu at the left side of the screen.
 a. This opens the "User Management" screen.
- 2. Navigate to the user whose permissions should be edited and **click the check box**.
- 3. Click on the Edit Permissions button in the top-left of the screen.
 - a. This opens the "Edit Permissions" window.

Note: Study membership role is inherited throughout the study team lists and can be updated on the individual entity level to increase the user's access.

TI CTMS USER GUIDE v1.2

🖶 User Management						arch Q
«	User Management					
F	🔘 Invite 🧪 Edit 🕕 Deactivate	🖬 Edit Permissions 😒 Resend Invite			c), Search
()	21 Users 1 Selected				test ti	
	Name	Status	Global Role	Email	TT Ended	-
TrialInteractive	🗹 👗 test ti			yogitest@ti.com	24 Sep 202	
	🛔 Linda Munn	(INVITED)		Lindø@ti.com	E Emai	
Deshboard	🗌 🛔 yog test	ACTIVE		yogtest123@ti.com	General Information	
Programs	CRA DEMO	ACTIVE		crademo@ti.com	Prefix First Name	Middle Name
Products	UAT First UAT Last	ACTIVE		dofourl@gmail.com	test	
A Studies	🛔 Elain Cusack	ewiteD		elain@email.con	Last Name	Suff
Organizations	🛔 George Smyth	CUTTOR		smytmichael@gmail.com	ti	
User Management	👗 Abhijit Kamble	ACTIVE		akamble@transperfect.com	Global Role None	
C Activities Library	🔄 🚨 Sufiya Sultana	ACTIVE		ssultana@transperfect.com	Status	Туре
Activity Plan Templates	💄 Lakshmi Kadiyala	ACTIVE		lkadiyala@transperfect.com	Invited	Regular
Milestone Templates	🗌 🛔 Mr. Kennon Atkeson	ACTIVE		katkeson@transperfect.com	User Since	Created By
	🛔 Mr. Owen Omoijuanfo	ACTIVE		oomoijuanfo@transperfect.com	24 Sep 2021	admin admin
	🔒 Mrs. Susan Geers-Meiners	ACTIVE		sgeersmeiners@transperfect.com	Preferred Languages 0 La	inguage
	🛔 Mrs. Sandesh Visoriya	ACTIVE		svisoriya@transperfect.com		
	Anncy Drew	CONTROL		abdul,anwer@gmail.com	Preferred Communication	n Method
	A Hope Weisser	ACTIVE		howeisser@transperfect.com	Time Zone	Best Contact Time
	Abdul Anwer	ACTIVE		aanwer@transperfect.com		and the second second
	🛔 John Doe	ACTIVE, INACTIVE, INVITED		userT@mail.com		
	🔄 🛔 John Dae	ACTIVE, INACTIVE, INVITED		test@mail.com	Contact Information	
	🔲 🛔 John Test	ACTIVE INACTIVE INVITED		user@mail.com	Phone Numbers	
	admin admin	ACTIVE		ctms.admin@transperfect.com		ecords available
					Email	
					Primary	

- 4. Navigate through the list of organizations below or use the search box to find the sponsor.
- 5. Expand the selected organization and select the appropriate product or study.
- 6. Assign the user a specific role associated with that product or study.
- 7. Click on the Save button the bottom of the edit permission window.

	User Managemen	Edit Permissions		× ×		
E	Invite PEdit OD D 23 Users 1 Selected Name	Π Lest ti ☑ yogitest@ti.com			Q, Search Email	. .
TrialInteractive	Hope Weisser	Global Role Internal User (Manager)	~		hopeweisser@ti.com yogitest@ti.com	
Dashboard Sponsors Programs	Linda Munn	Levels Permissions			Linde@ti.com yagtest123@ti.com	
Products	CRA DEMO		ned Permissions	Q Search	crademo@ti.com dofourl@gmail.com	
Organizations Contacts	Bain Cusack	None Apply 117 Items 1 Selected	to Selected		elain@email.con	
User Management	George Smyth	Levels		Role	smytmichael@gmail.com	
Activities Library	Abhijit Kamble	Tremors Study		None	akamble@transperfect.com ssultana@transperfect.com	
Milestone Templates	Lakshmi Kadiyala	▲ AMed42021		None V	lkadiyala@transperfect.com	
	Mr. Owen Omoljuanfo	Diagnova 🕹 Diagnova		None 🗸	oomoijuanfo@transperfect.com	
	💄 Mrs. Susan Geers-Mein			Clinical Study Manager test	sgeersmeiners@transperfect.com	
	📄 🦀 Mrs. Sandesh Visoriya	Global Permissions		Clinical Study Manager (CSM) CRA Manager	svisoriyø@transperfect.com	
	Nancy Drew	Permissions Invite/Manage Users	Description This is permission for inviting/Managing Users	Clinical Research Associate (CRA)	abdul.anwer@gmail.com	
	A Hope Weisser	in the manage over a	The is permanent of interly managing over	Contract CRA	howeisser@transperfect.com	
	💄 Abdul Anwer			Country Manager (CM)	aanwer@transperfect.com	
	📃 💄 John Doe			<u>Clinical Trial</u>	userT@mail.com	
	🔒 John Doe				test@mail.com	
	📃 🚨 John Test		Cancel Save		user@mail.com	
	👗 admin admin				ctms.admin@transperfect.com	

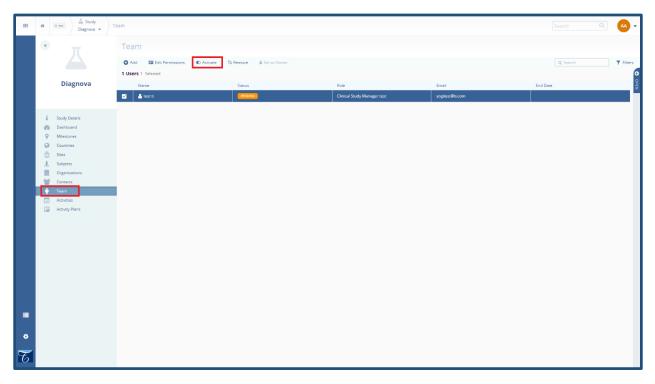


Version 1.0 Page 130 of 130

Note: Turning on **Invite/Manage** Users under Global Permissions will allow for the user to create and invite users to the system.

12.4 Study Team Management

- 1. Navigate to the study name and click on it.
- 2. Click on the **Team** link in the Navigation menu at the left side of the screen.
 - a. This opens the "Team" window.
- 3. Select the username from the list displayed that has the status of **PENDING.**
- 4. Click on the Activate button in the top-left of the screen to activate the user.



Please note that only study team members listed as Unblinded team members will be able to see unblinded study data where applicable. An Unblinded Clinical Study Manager may assign study team members to Unblinded roles but a Blinded Clinical Study Manager cannot.

12.5 Deactivating a User Account

- 1. Click on the **User Management** link in the Navigation menu at the left side of the screen.
 - a. This opens the User Management screen.
- 2. Navigate to the user you want to deactivate, click the check box before the username.
 - a. This opens the quick view on the right side of the screen.
- 3. Click on the **Deactivate** button in the top-left of the screen.



a. This opens the Deactivate Users window.

T R I A L INTERACTIVE

4. Click on the **Deactivate** button in the **Deactivate user's** window.

Note: The reverse of this action can be done to activate a user.

	User Management						arch Q
1		User Management					
	Ŧ	🗿 Invite 🥒 Edit 🕢 Deactivate	Edit Permissions El Resend Invite				search T
	()	21 Users 1 Selected				yog tes	t
		Name	Status	Global Role	Email	YT Adhe	
	TrialInteractive	📋 👗 test ti	INVITED.		yogitest臣ti.com	22 Sep 202	
		📋 🔺 Linda Munn	INITED		Linda@ti.com	Email Email	
	Dashboard	🔄 🏝 yog test				General Information	
	Sponsors Programs	CRA DEMO	_	4	mo@ti.com	Prefix First Name	Middle Name
	Products	UAT First UAT Last	Deactivate Users		□ × ni⊚gmail.com	yog	
	A Studies	🔒 Bain Cusack	Do you want to deactivate the following use	10)2	Pernail.con	Last Name	Suff
	Organizations	George Smyth	User(s) yog test	r(s)r	nichael@gmail.com	test	
	Contects User Management	💼 📄 👗 Abhijit Kamble	Usents) yog test		ble@transperfect.com	Global Role	
	Activities Library	🔄 🛔 Sufiya Sultana			ina@transperfect.com	None	
	Activity Plan Templates	👗 Lakshmi Kadiyala			ala@transperfect.com	Status Active	Type Regular
	Milestone Templates	📕 Mr. Kennon Atkeson			son@transperfect.com	User Since	Created By
		👗 Mr. Owen Omoijuanfo			ijuanfo@transperfect.com	22 Sep 2021	admin admin
		🔄 💄 Mrs. Susan Geers-Meiners	Cano	Deactivate	smeiners@transperfect.com	Preferred Languages 0 La	inguage
		🛔 Mrs. Sandesh Visoriya	Caro	Descovate	iya@transperfect.com		
		A Nancy Drew	INVITED		abdul.anwer@gmail.com	Preferred Communication	Method
		A Hope Weisser	ACTIVE		howeisser@transperfect.com		
		Abdul Anwer	ACTIVE		aanwer@transperfect.com	Time Zone	Best Contact Time
		👗 john Dae	ACTIVE, INACTIVE, INVITED		userT@mail.com		
		🗂 💄 John Doe	ACTIVE, INACTIVE INVITED		test@mail.com	Contact Information	
		🛔 John Test	ACTIVE INACTIVE INVITED		user@mail.com		
		🔄 🛔 admin admin	ACTIVE		ctms.admin@transperfect.com	Phone Numbers	ecords available
						Email	
						Primary	
						yogtest123@ti.com	2

12.6 Resending a User's Invite

- Click on the User Management link in the Navigation menu at the left side of the screen.
 a. This opens the User Management screen.
- 2. Navigate to the user whose invitation you want to resend and click the check box.
 - a. This opens the quick view on the right side of the screen.
- 3. Click on the **Resend Invite** button in the top-left of the screen.
 - a. This opens the Resend Invite window.
- 4. Click on the **Resend** button in the **Resend Invite** window.

Note: You can only resend an invite to a user with an Invited status.

TI CTMS USER GUIDE v1.2

🖷 🖉 User Management							iearch Q	
	User Management							
Ŧ	🗿 Invite 🧪 Edit 🗇 Descrivate	O Imète 🖋 Edit © Descrivete 🖽 Edit Permissions 🖸 Resend Invite						
	21 Users 1 Selected					test t		
	Name	Status	Global Role	Email		(п) 💷		
TrialInteractive	🗹 💄 test ti	(INVIED)		yogite	est@u.com	24 Sep 2		
	🔹 🛓 Linda Munn	(MINA)		Linda	@tl.com	- Er	nad	
Deshboard	🗌 🛔 yog test	ACTIVE		yogte	st123@ti.com	General Informatio	on	
Sponsors	CRA DEMO	_			mo@ti.com	Prefix First Nam	e Middle Name	
Products	LIAT First UAT Last	Resend Invite		×	n@gmail.com	test		
A Studies	👗 Elain Cusack	Do you want to resend an invite to the	fallen (an and 12		Pernail.con	Last Name	Suffi	
Organizations	George Smyth	User(s) test ti	ronowing user(s):		nichael@gmail.com	ti		
User Management	🖉 👗 Abhijit Kamble	osens) test u			ble@transperfect.com	Global Role		
Activities Library	Sufiya Sultana				na@transperfect.com	None		
Activity Plan Templates	🔔 Lakshmi Kadiyala				ala@transperfect.com	Status Invited	Type Regular	
Milestone Templates	🗌 👗 Mr. Kennon Atkeson				son@transperfect.com	User Since	Created By	
	🛔 Mr. Owen Omoijuanfo				juanfo@transperfect.com	24 5ep 2021	admin admin	
	🔄 🛔 Mrs. Susan Geers-Meiners		Cancel Resend		smeiners@transperfect.com	Preferred Languages 0 Language		
	🛔 Mrs. Sandesh Visoriya				ya@transperfect.com			
	Nancy Drew	(WILCO)		lubde	lanwer@gmail.com	Preferred Communicat	ion Method	
	📕 Hope Weisser	ACTIVE		howe	isser@transperfect.com			
	Abdul Anwer	ACTIVE		aanwo	er@transperfect.com	Time Zone	Best Contact Time	
	🔷 👗 John Doe	ACTIVE, INACTIVE, INVITED		userT	@mail.com			
	🗂 🌡 John Doe	ACTIVE, INACTIVE, INVITED		test@	mail.com	Contact Informatio	n	
	👗 John Test	ACTIVE INACTIVE INVITED		userd	Qmail.com			
	📋 🛔 admin admin	ACTIVE		ctms.	admin@transperfect.com	Phone Numbers		
						Email		
						Primary		

12.7 Removing Users from a Team list

- 1. Navigate to Studies screen and click on the name of the study whose team you wish to edit.
- 2. Click on the Team link in the Navigation menu at the left side of the screen.
- 3. Navigate the user you want to remove from a team list and select them.
- 4. Click the **Remove** button in the top-left of the screen.
 - a. This opens the **Delete user from a Team** window.
- 5. Click on the **Remove** button in the bottom of the **Delete user from a Team** window.



TI CTMS USER GUIDE v1.2

