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LIFE SCIENCES

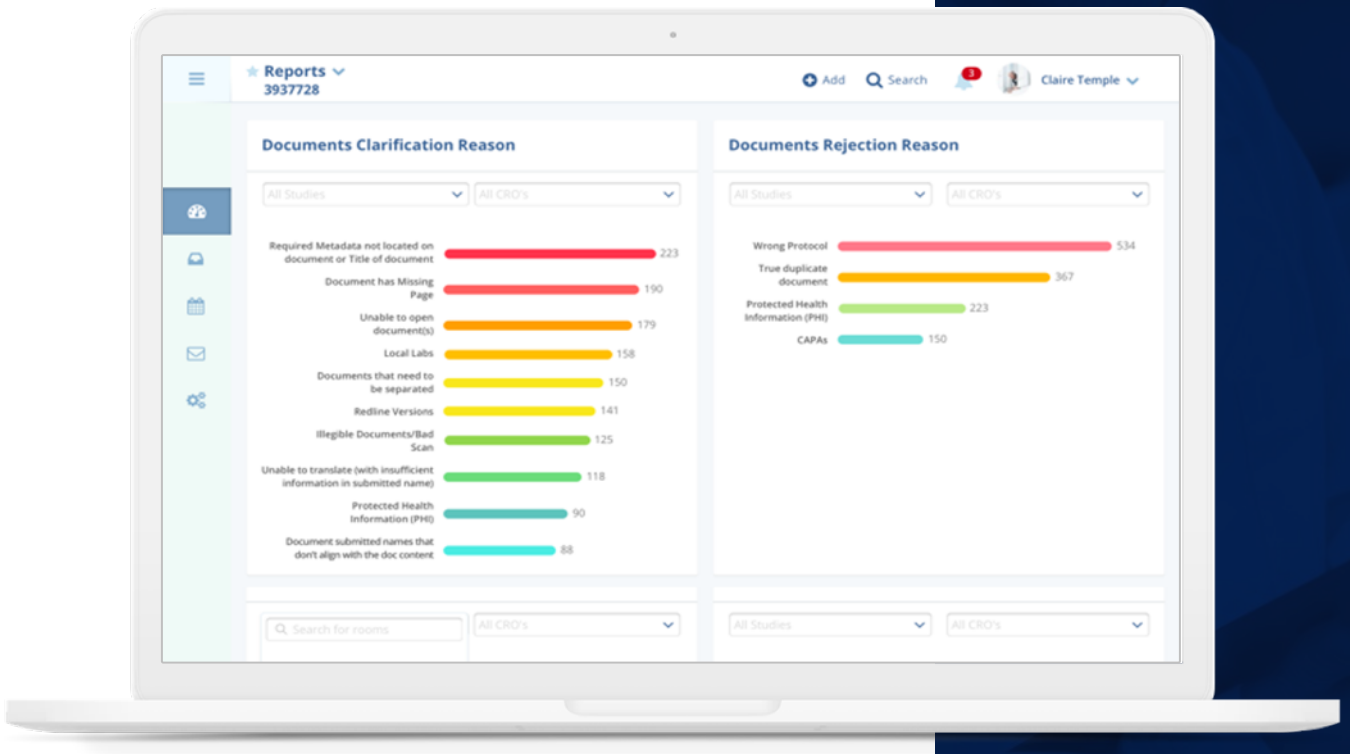
September 2020

TRIAL INTERACTIVE PRE-RELEASE WALKTHROUGH

ETMF, SSU, CMS

10.1 Release Plan

Deliverable	Planned Date
Pre-Release Notes	July 24
Release Candidate	September 4
PRE-RELEASE Sandbox Available	September 9
Training Sessions	September 9-18
Validation	September 18-23
Release Notes	September 23
General Availability	September 23
Multi-Tenant Upgrade	September 25
TI 10.1.1 Patch	October 16



10.1 ETMF UPDATES

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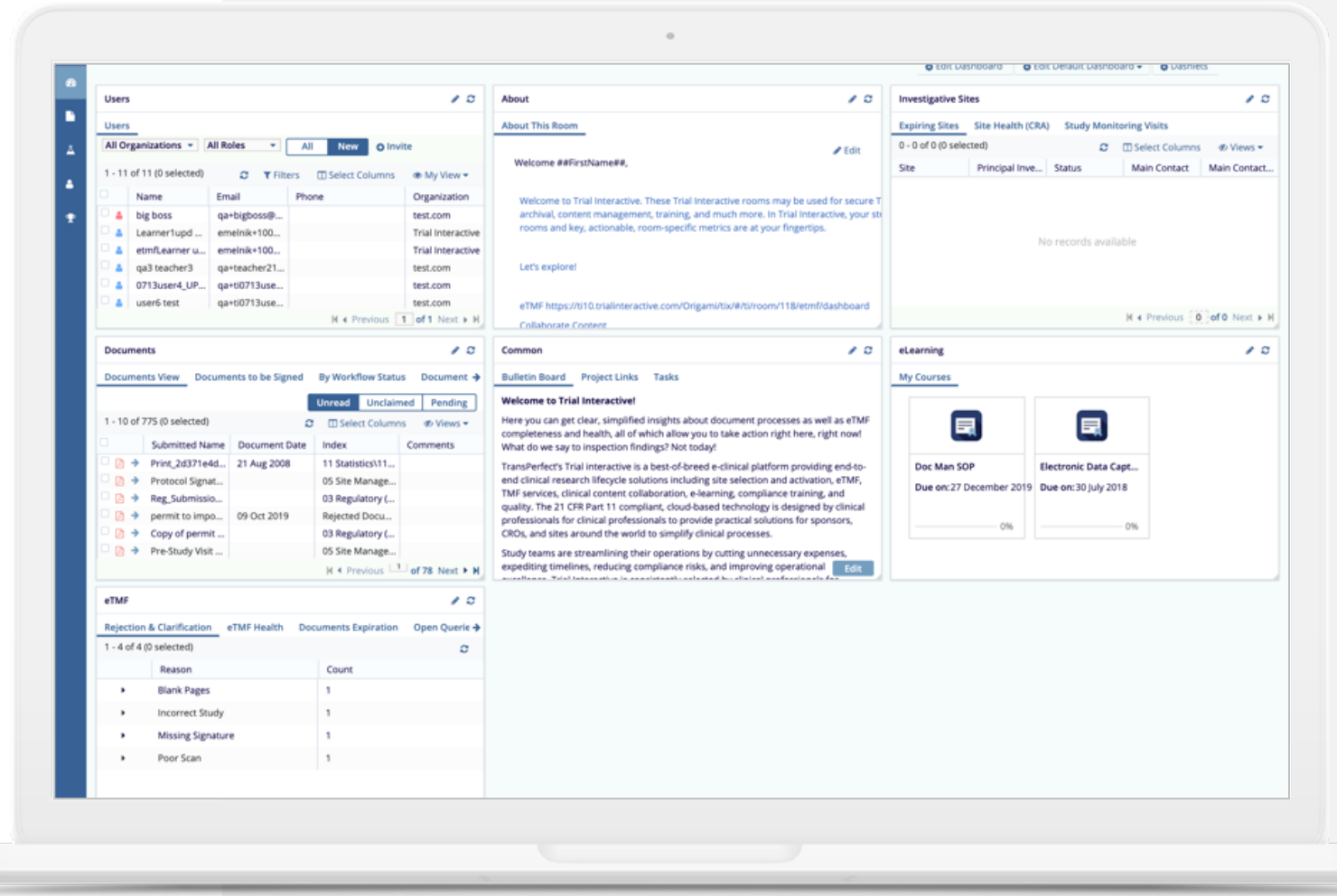
10.1 Dashboards

Three-Column Dashboard Layout

Trial Interactive 10.1 brings back the 2 and 3 column look to the dashboards as well as the single column tabbed view introduced in TI 10. This provides more flexibility, allowing dashlets to be repositioned and configured to fit the needs of your team.

- All standard TMF dashlets are available to show in different chart styles, such as donut, horizontal and vertical bar chart layouts.
- If project training is required for access it is clearly shown in an eLearning dashlet with courses listed.
- For Content Management customers, the in-progress collaborative reviews are shown, as are popular documents, favorites, approvals, and required signatures.

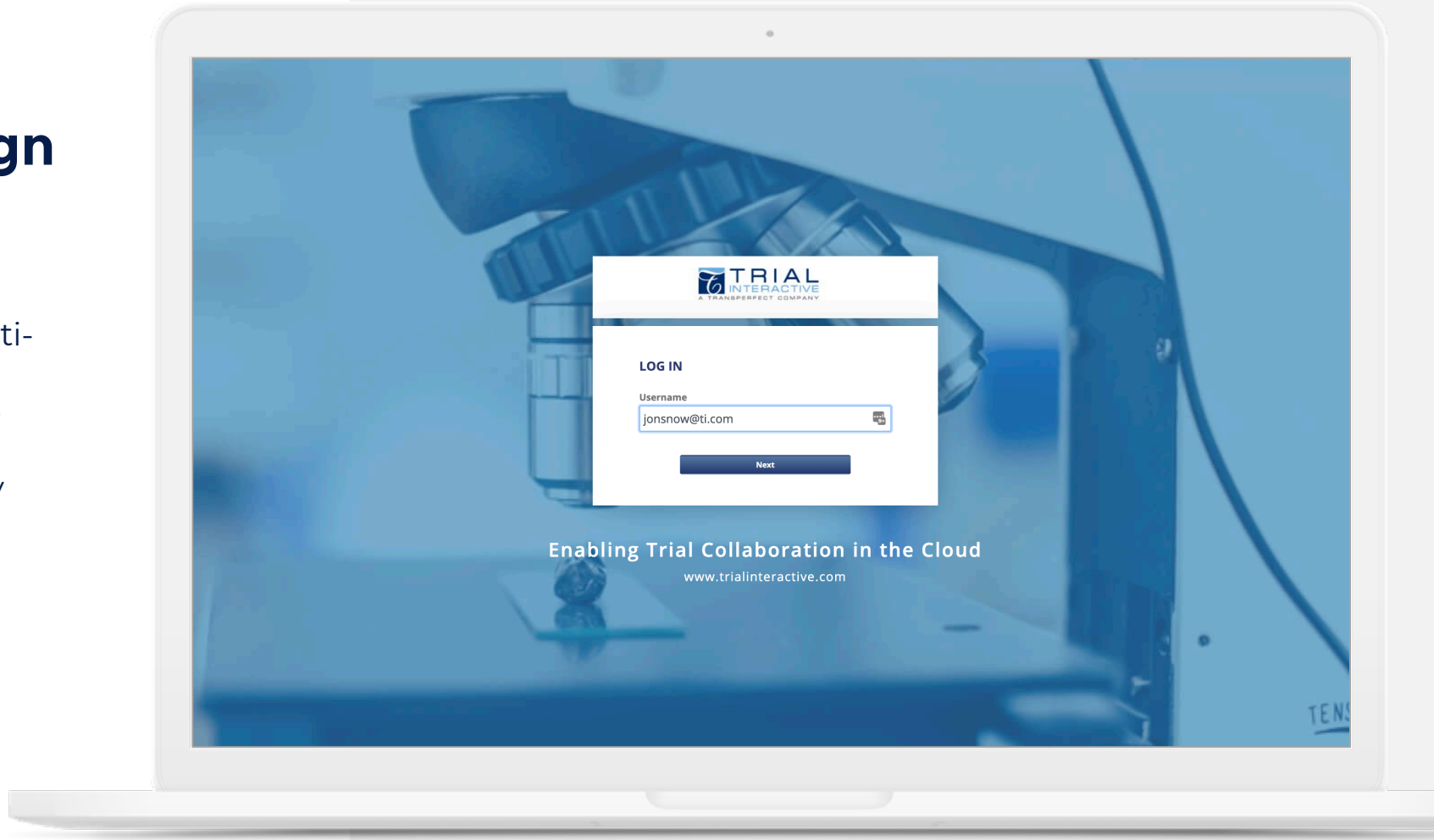
Finally, administrators can set the default dashlet layout for each major role directly from this page, defining it for all users of the eTMF or room.



10.1 Access

Multi-Tenant Single Sign On

Introduced in 10.1 is support for SAML Federated Single Sign On on the TI multi-tenant platform. Now, all customer domains on multi-tenant can configure single-sign on through their own Corporate Directory, as well as 3rd party IAM providers such as Okta, OneLogin, Ping, and others.



10.1 eTMF Health

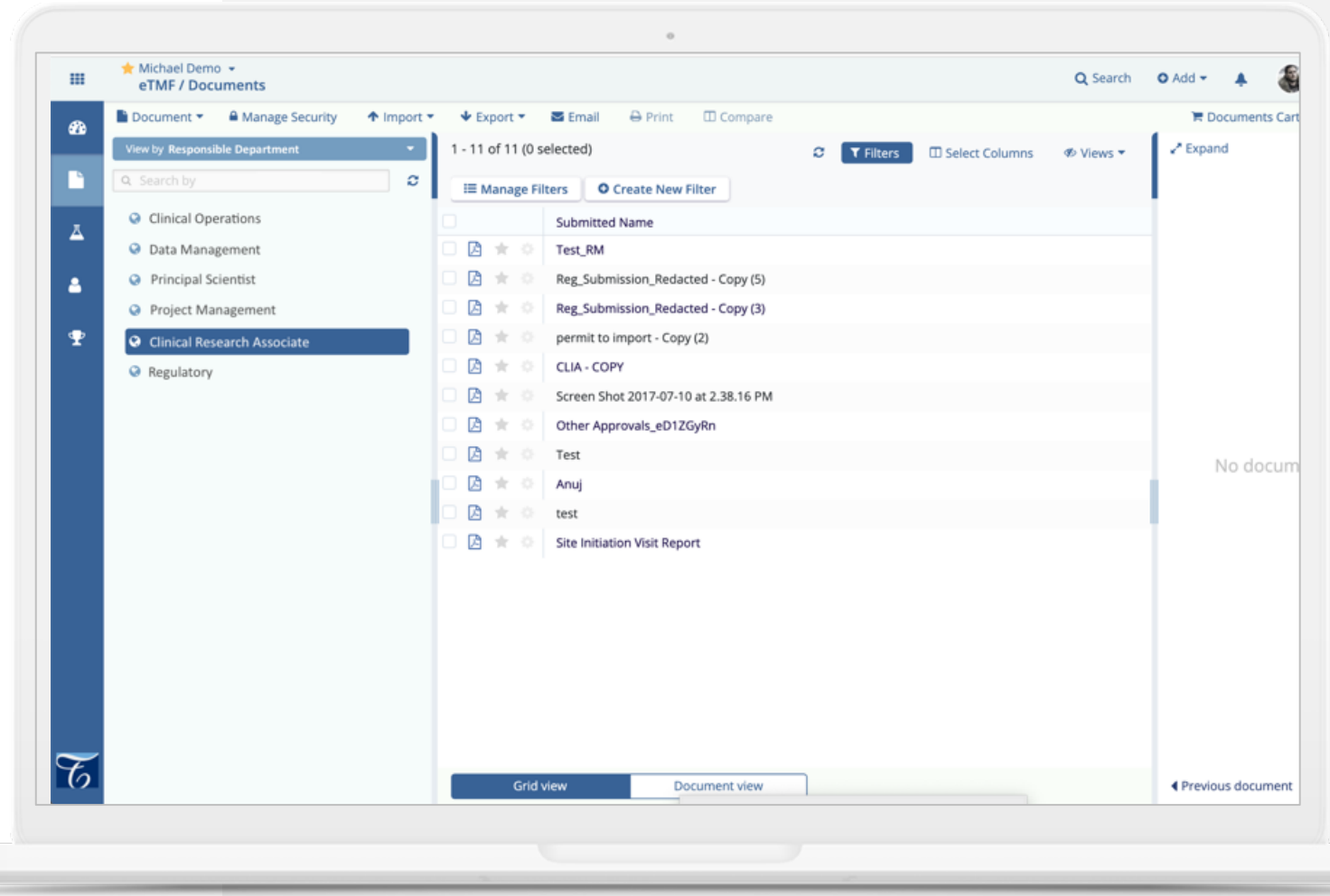
Department Views

One of the business challenges with eTMF is the ability to ensure that documents are submitted in a timely fashion as the trial progresses. To ensure that happens, it is important to understand the person or department responsible for the authoring, collection, and submission of each required document and placeholder.

While CRAs are often responsible for document collection from the sites, many other documents must be collected, both from internal groups, from regulatory authorities, IRBs/IECs, and partners.

10.1 introduces the definition of Responsible Parties and Owners to Trial Interactive. For each Document Type, the responsible group or person may be defined These definitions may be set up using groups within the room for a flexible assignment of ownership when the study is defined.

The ‘By Department’ and ‘Documents’ views are introduced, to provide a simplified way for admins and users to see which placeholders and required documents they must submit. This assists the eTMF team in ensuring the timeliness and quality of all document submissions to the eTMF.

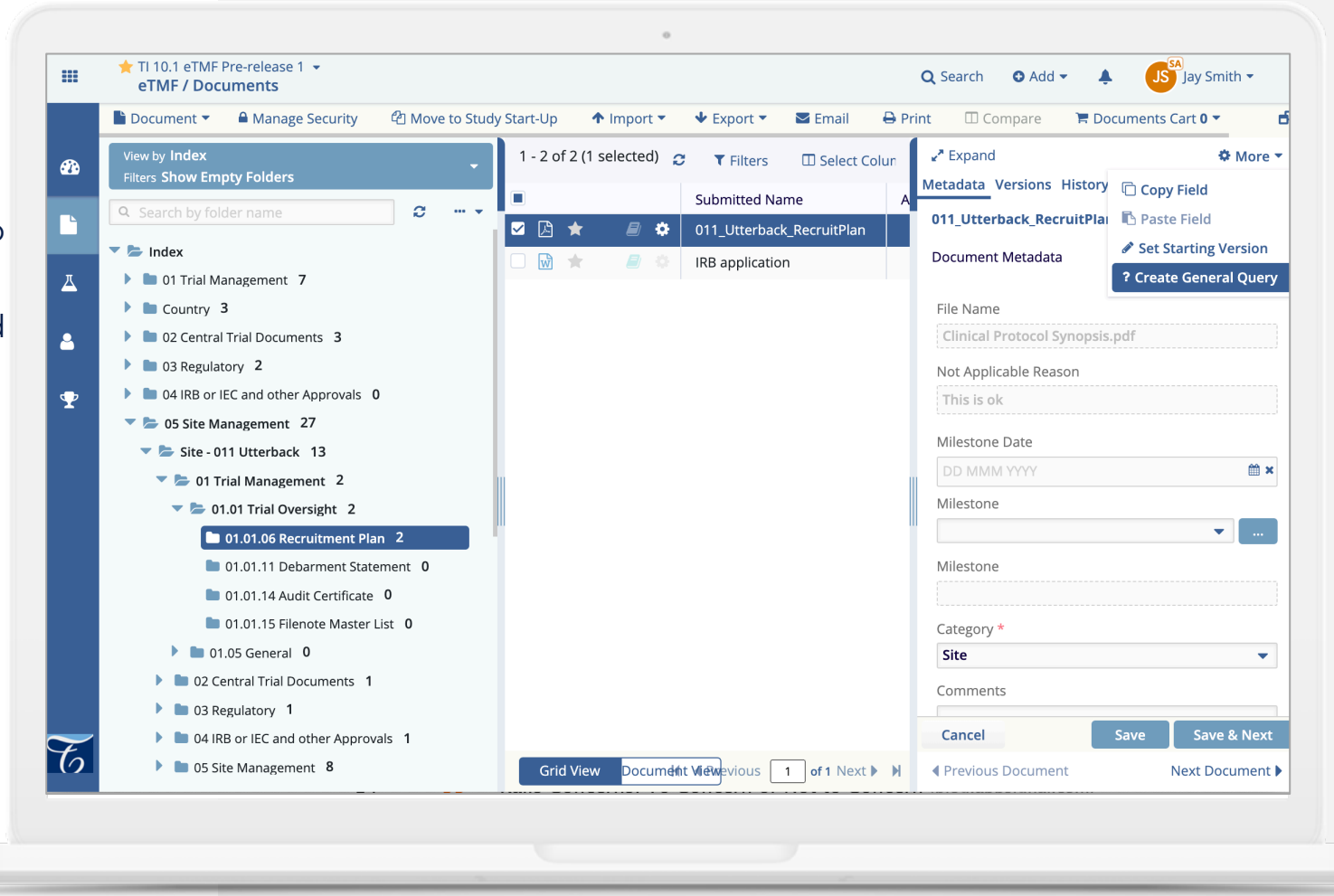


10.1 Query

Final Document Query

Queries are a critical feature in TI, and in 10.1 Queries will become much more flexible. Currently queries can only be used as part of a workflow, but 10.1 changes all of that. Queries can now be opened against a document at any time, for purposes of clarification or to prompt for document replacement.

- Only an Admin or Document Manager can raise and resolve a query against a Final document through a simple right-click. Once raised, the queries may be viewed by status from an All Queries view and are assigned by default to the submitter or the person who last progressed the workflow.
- The standard query workflow is then followed, allowing the responder to clarify the query, or respond with updated content. All back and forth is captured in the document audit trail as normal. Documents may be emailed in or attached directly to the query response from within Trial Interactive.
- Documents with open queries will show with an icon in the index and working views, and queries may be filtered by the responders by site, country, issue type, and other configurable filters.



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10.1 Search

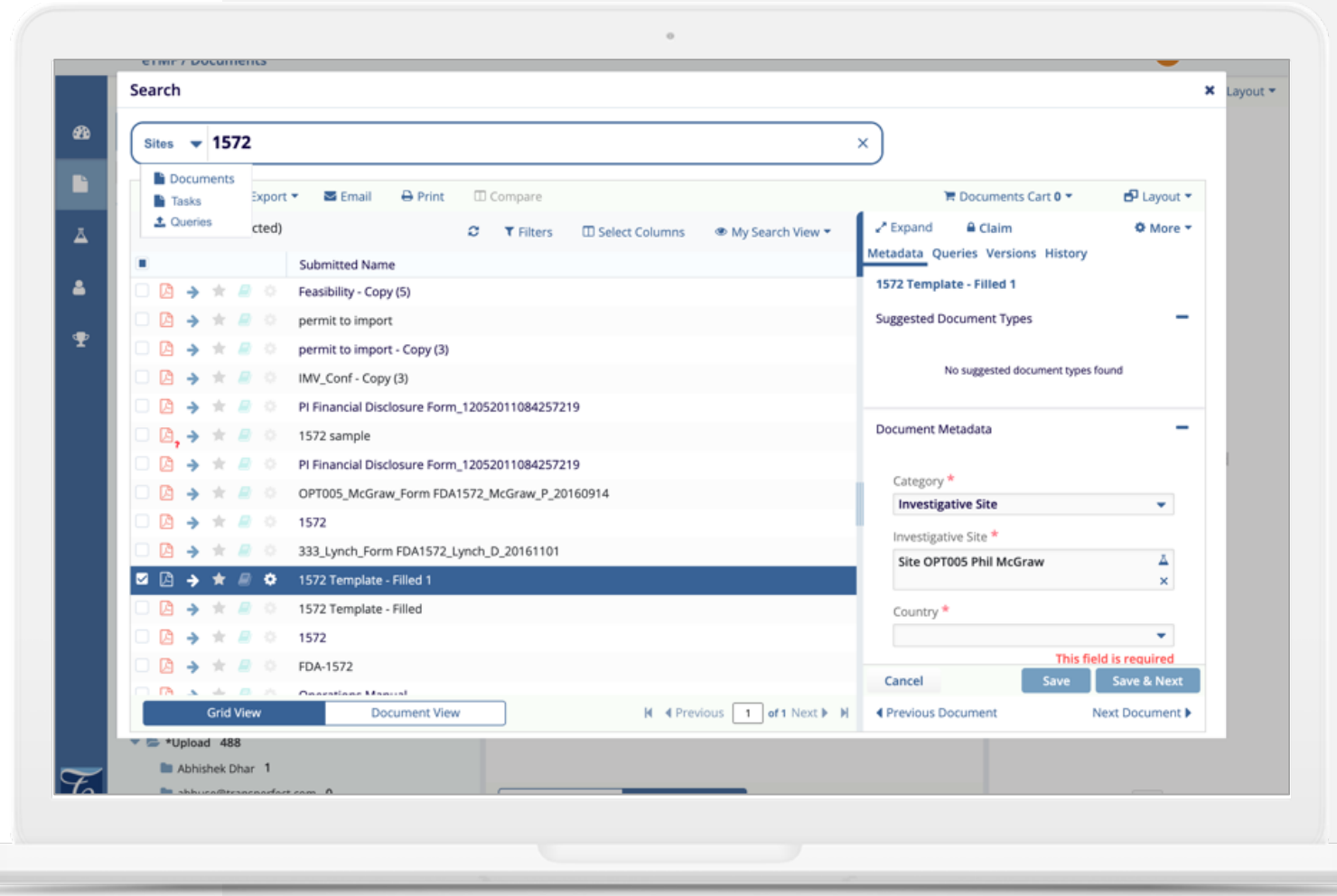
Improved Metadata Search

In 10.1, additional items may be searched that go beyond documents, including queries, tasks, and users. These may be selected using a simple dropdown next to the search box.

A more advanced metadata search is also available that provides the ability to search on key fields that are very common. Note that the room may still be configured to limit the global search to just a few metadata fields. This improvement provides more fine-grained control to a user. For Example, a user may search against all 1572 forms in a specific Country containing a specific piece of text.

- Document ID
- Name
- Title / Submitted Name
- Submitted Date
- Investigative Site
- Country
- Within the Text of the Document

Any other metadata field needed, configured in the search panel by each user.

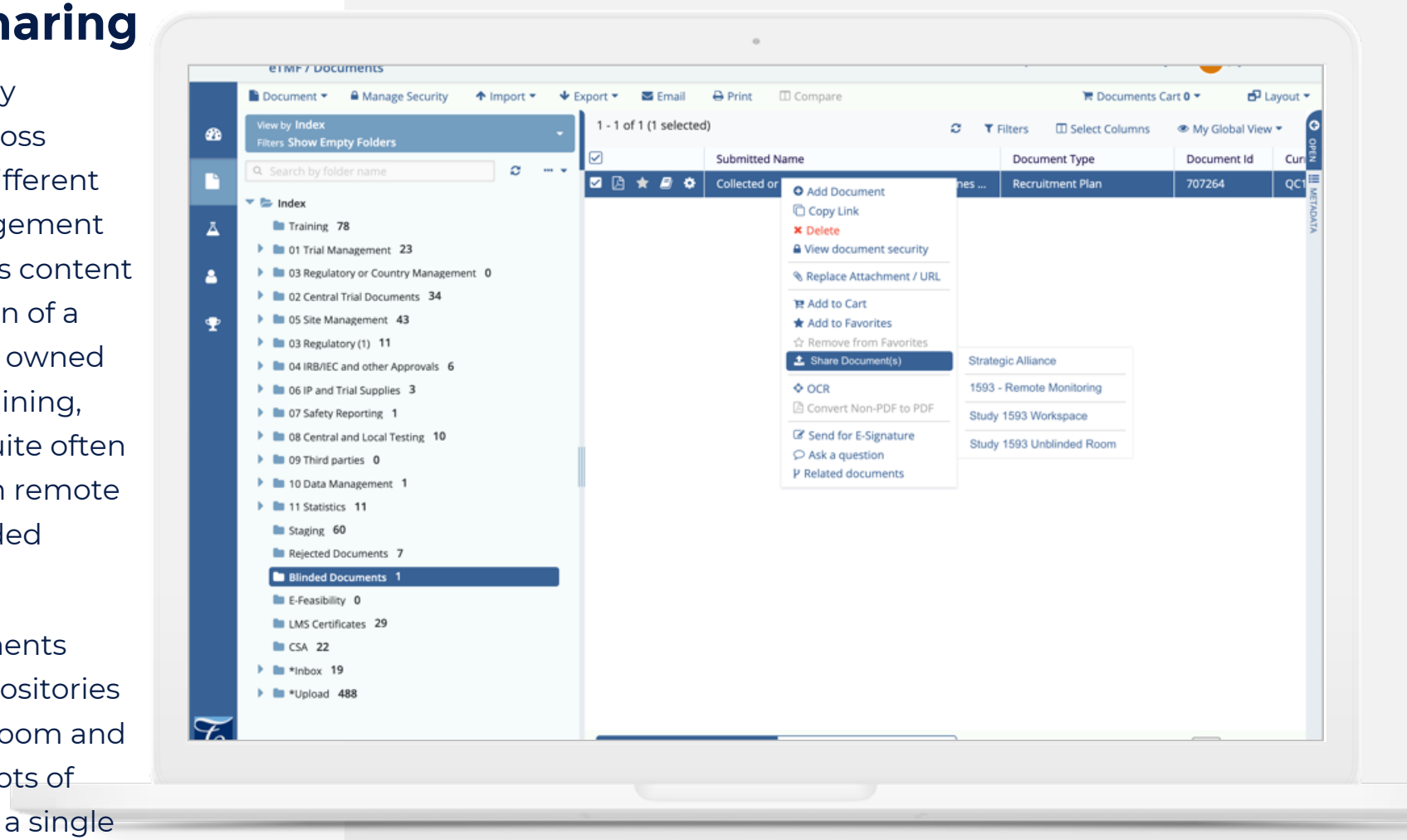


10.1 Sharing

Cross-Room Document Sharing

Content Management in life sciences is a very complex set of relationships that happen across multiple repositories of content, owned by different business units. Clinical needs content management and TMF system, which authors and captures content generated during the planning and execution of a Clinical Trial. Other repositories exist that are owned by Quality, Regulatory, R&D, Commercial, Training, Medical Writing, and many others. Finally, quite often Clinical needs access to site documents from remote monitoring workspaces, and to keep unblinded content in a separate repository.

10.1 introduces the capability to share documents easily, in a controlled fashion, between TI repositories called Rooms. This sharing is configured by room and may be enabled many to many, to allow for lots of content sharing scenarios, including sharing a single document to many eTMFs, from many sites to a single eTMF, and from an eTMF to other groups.



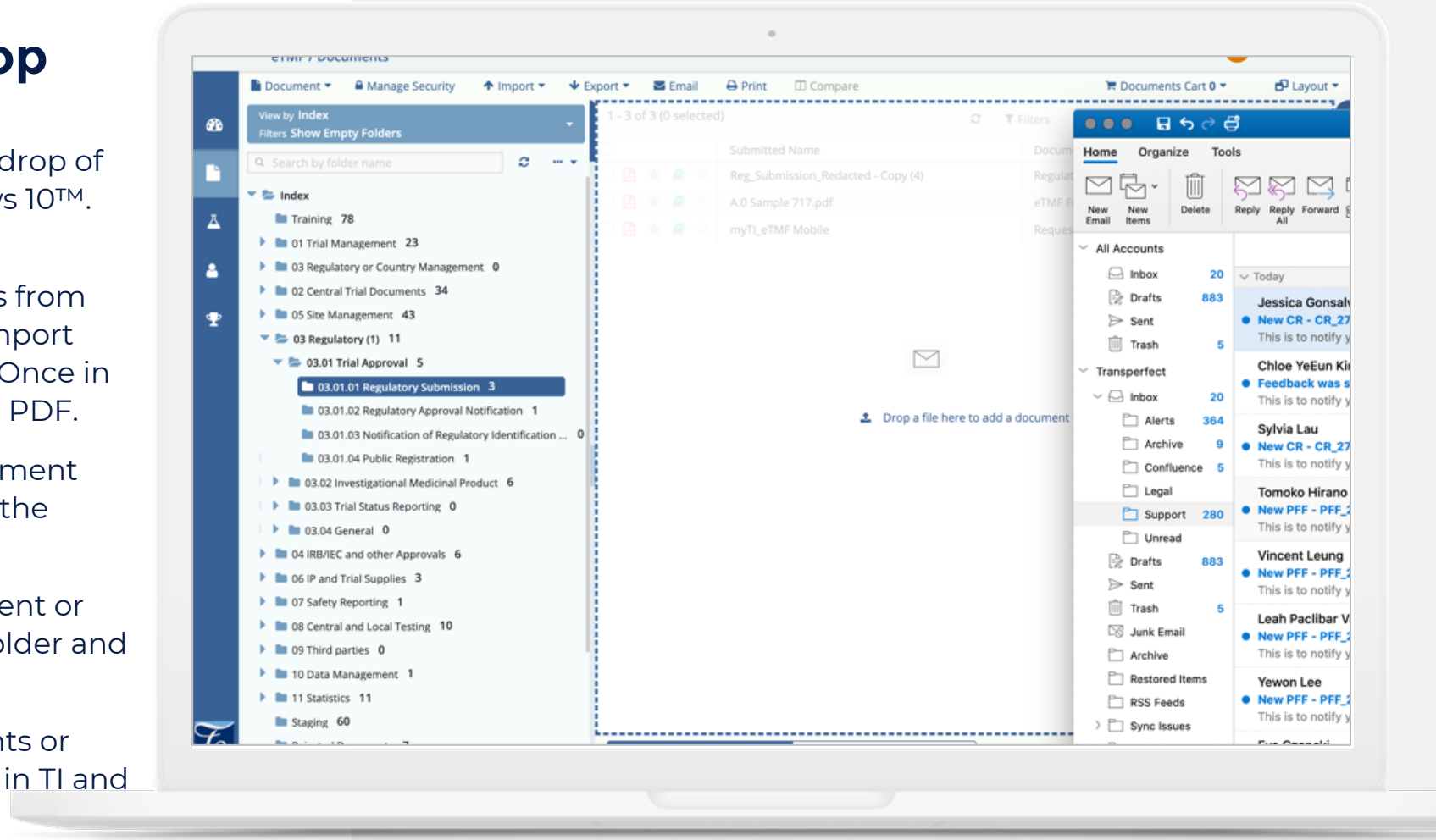
10.1 Outlook

MS Outlook Drag and Drop

10.1 now supports Microsoft Outlook™ interoperability, fully supporting drag and drop of documents and mail messages in Windows 10™. This provides the following:

- You can drag and drop email messages from MS Outlook into TI and the email will import along with all document attachments. Once in TI, MSG files may be easily converted to PDF.
- You can drag and drop individual document attachments from an email into TI and the documents will import.
- You can drag and drop a single document or email message onto a folder or placeholder and it will auto-classify.
- You can drag and drop many documents or email messages into the import modal in TI and they will all load into the import box.

Some browsers such as Mozilla Firefox™ may require an Outlook plug-in to fully support this feature. Chrome and Edge do not.



10.1 Certified Copy

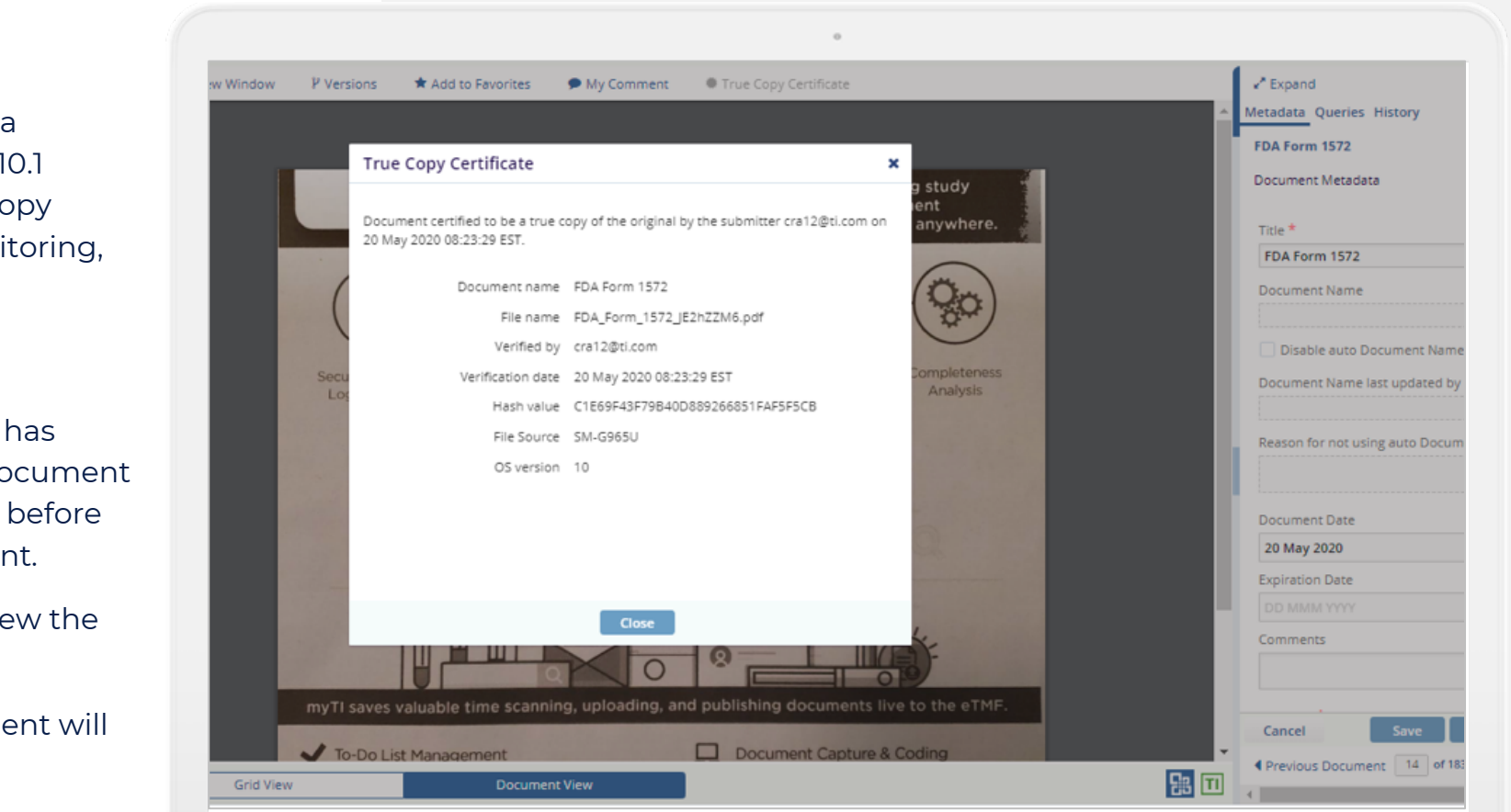
Certified Electronic Copy

For situations where the original paper copy of a document may be destroyed or unavailable, TI 10.1 introduces the capability to ensure a certified copy workflow from eTMF, Collaborate, Remote Monitoring, and other room types in TI.

With this feature:

- You can upload a document in a room that has enabled true copy, and you can verify the document uploaded and review copy certification text before providing credentials to certify the document.
- You can review a certified document and view the details related to that certification.
- If you edit a certified document, the document will no longer be a certified copy.
- The text used as the certification criteria is configurable by room, as well as define a default reason.

This feature also works in the myTI mobile app.



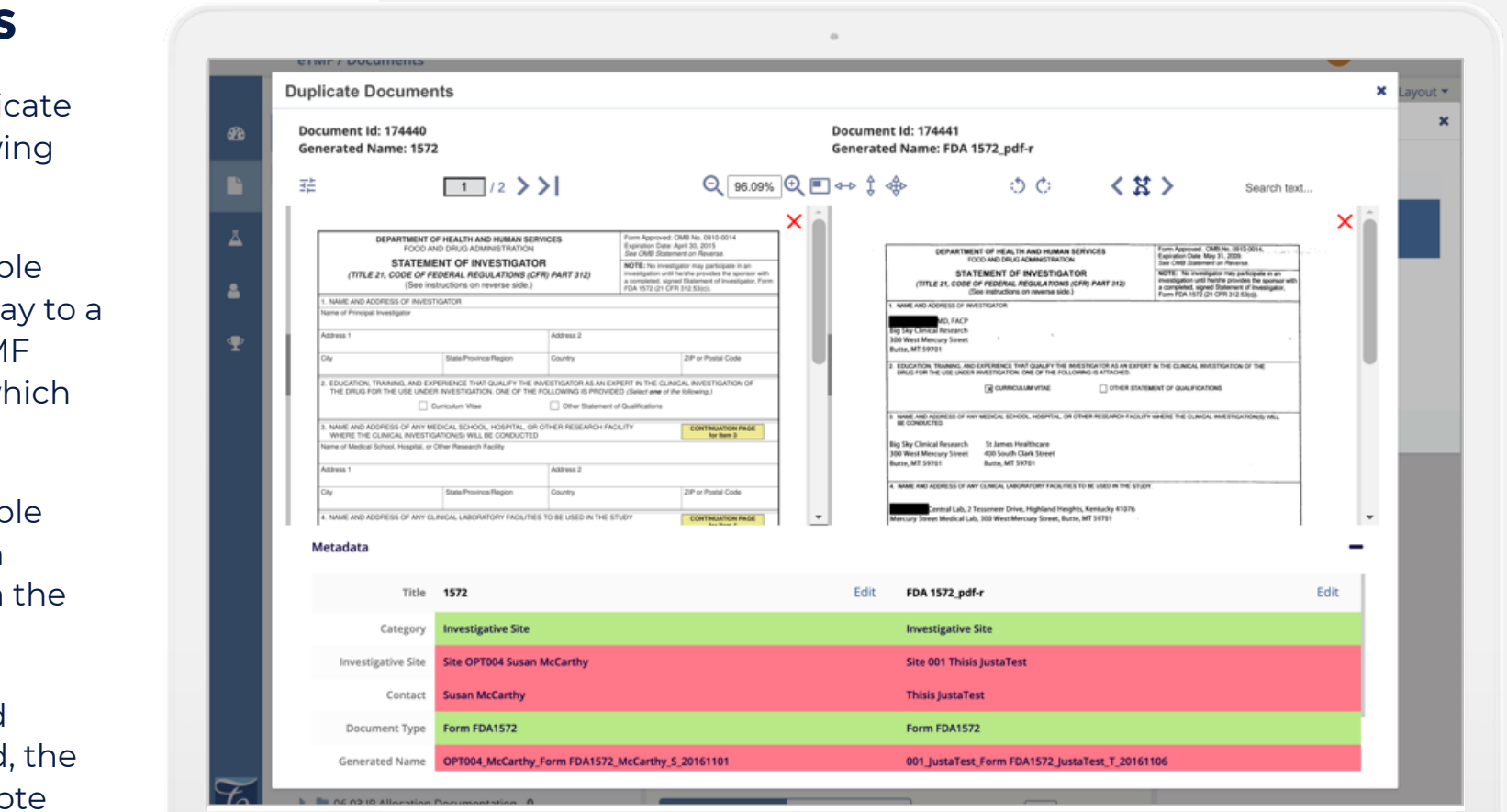
10.1 Duplicates

Flexible Duplicate Checks

10.1 introduces more flexibility around duplicate checks, improving the process in the following ways:

- Documents are now flagged for a possible duplicate if they are identical in every way to a document that already exists in the eTMF room (they have the same hash value which means the content is identical).
- Documents are now flagged for a possible duplicate if there is a document with an identical generated name at any step in the QC workflow process.

These flagged documents can be identified through an icon, and once they are claimed, the user is now prompted to compare them. Note that the user may opt to ignore the flag, if the document is known to be a duplicated site document for example.



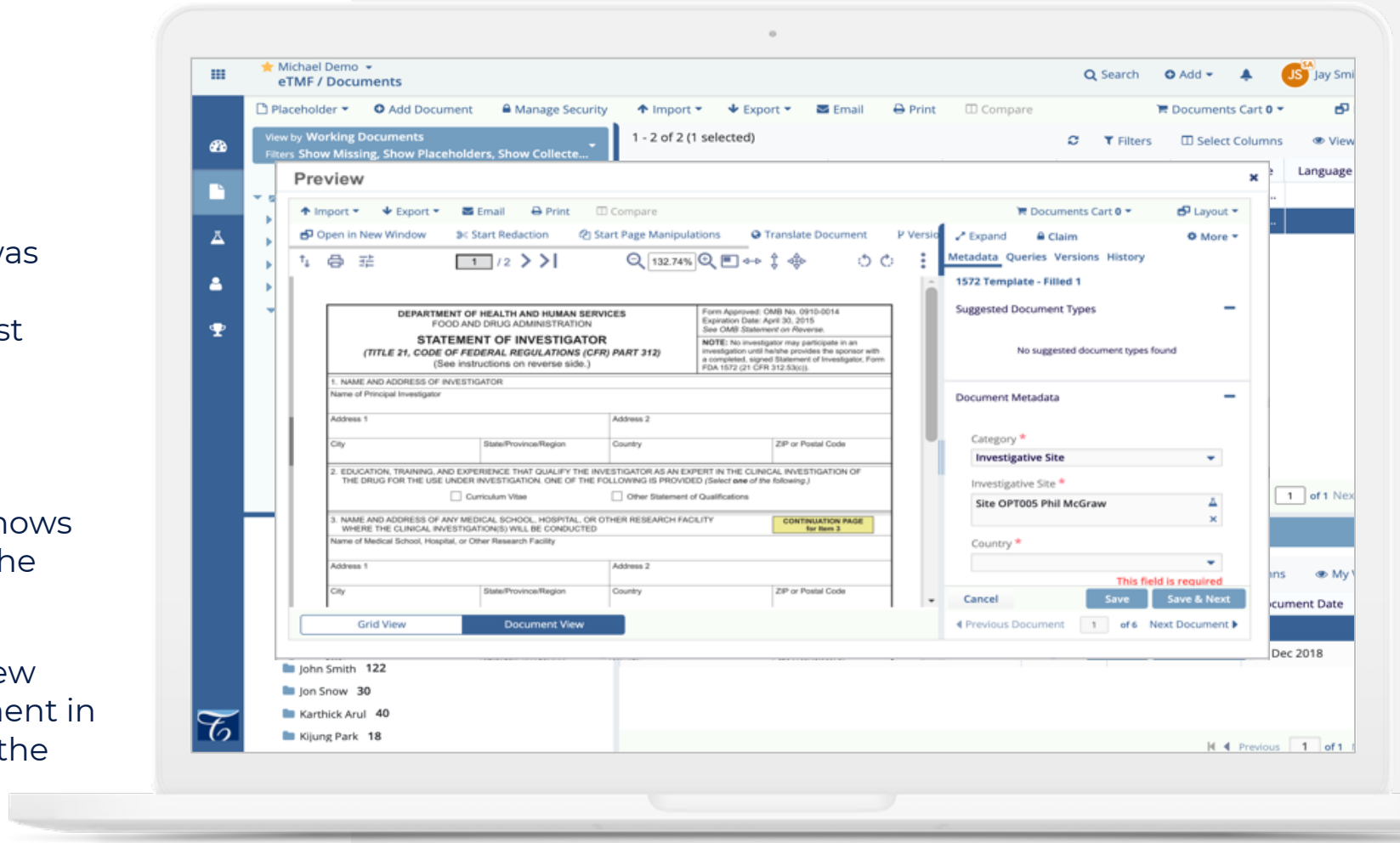
Potential Duplicates

10.1 Working View

Working Documents Preview

In TI 10, the Working Documents view was introduced to provide a simpler, more comprehensive index that shows not just final documents, but also collected documents and placeholders / required documents with a standard eTMF index structure. This view also introduced the Staging Area, a separate window that shows documents waiting to be classified via the eTMF workflow.

TI 10.1 introduces a simpler way to preview these documents, by selecting a document in the Staging Area and clicking, opening the document in a preview modal window alongside it's metadata.



10.1 Machine Learning

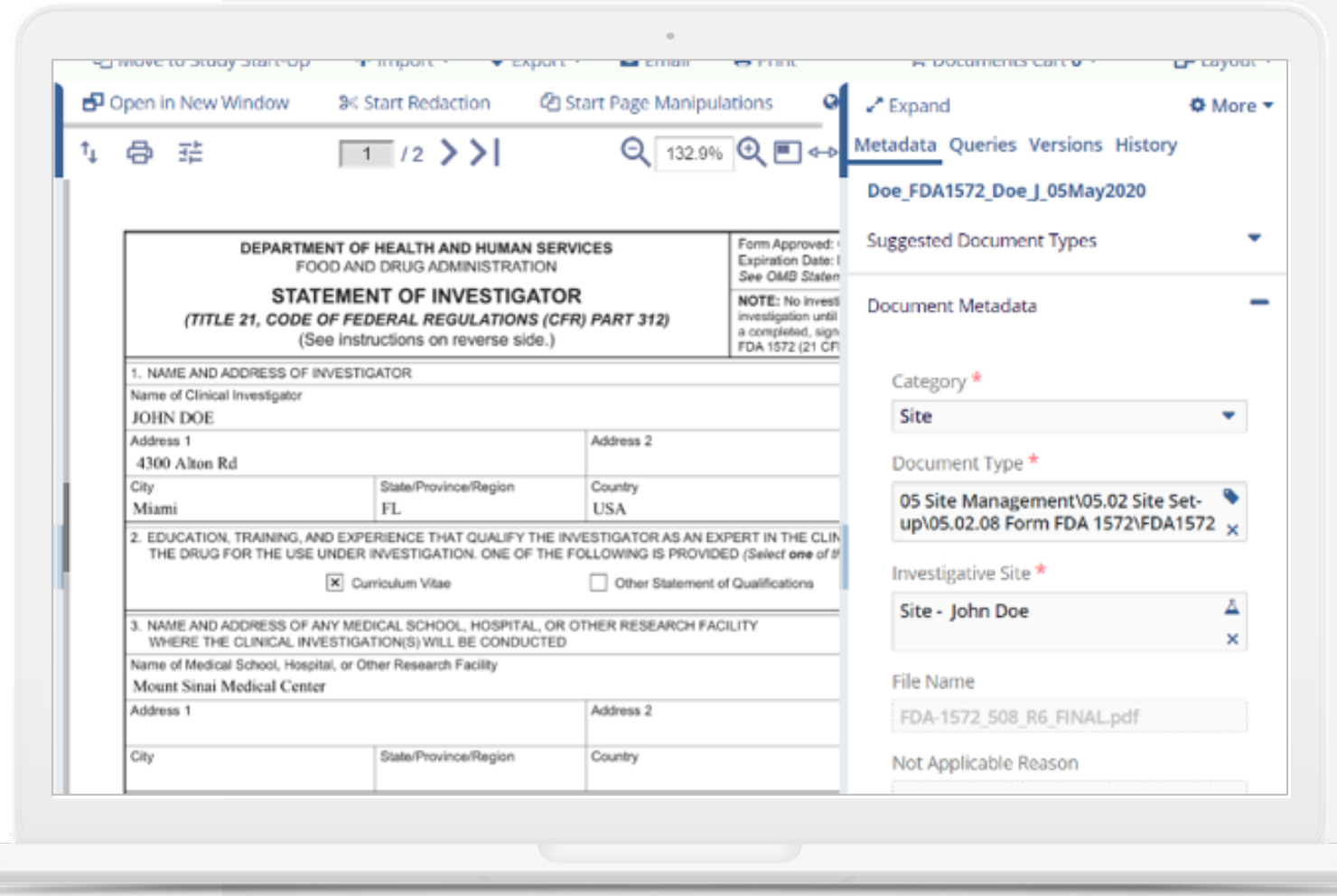
10.1 Document Classification and Metadata Extraction

Auto-classification of eTMF documents works well when enough document identification data has been collected and the machine learning model has been trained by the clinical team.

More powerful in 10.1 is the ability to recognize documents by identifying the document type, then extracting the metadata embedded within the document. This capability will identify investigator names, relevant dates, etc. and then prompt the user to verify and correct the additional pre-filled information.

10.2 eTMF Health Assistant

Automatically check for missing documents based on new documents added and look for outliers and anomalies. An automated Audit / eTMF health assistant. Flag issues like bad scans, poor rotation, page size issues and out of window documents, possible PHI, relevance, classification errors.



10.1 Reports

The following reports have been added in 10.1:

- **SSU Document History Report** - This new report provides a complete history from the time the document is uploaded in TI SSU module through various approval stages.
- **Document Placeholder Report** - This new report provides the complete history of any placeholders created, modified or deleted in the TI system.
- **Quality Review Report** - This new report displays the history documents (passed and failed) through the Quality Review module in TI.
- **Inventory and Completeness Report – Site** - The new report shall display the inventory and completeness of all documents (essential documents, non-essential documents, and placeholders) for Site category. The report shall also provide the Zone, Section and Artifact details related to each document type.
- **Inventory and Completeness Report – Country** - The new report shall display the inventory and completeness of all documents (essential documents, non-essential documents, and placeholders) for Country category. The report shall also provide the Zone, Section and Artifact details related to each document type.
- **Inventory and Completeness Report – Trial** - The new report shall display the inventory and completeness of all documents (essential documents, non-essential documents, and placeholders) for Trial category. The report shall also provide the Zone, Section and Artifact details related to each document type.
- **Inventory Report – Staging and Upload** - The new report shall display the inventory all documents for all categories that are available in the staging and inbox folder. This report will help take inventory of documents which are available in the system but have not been coded yet.

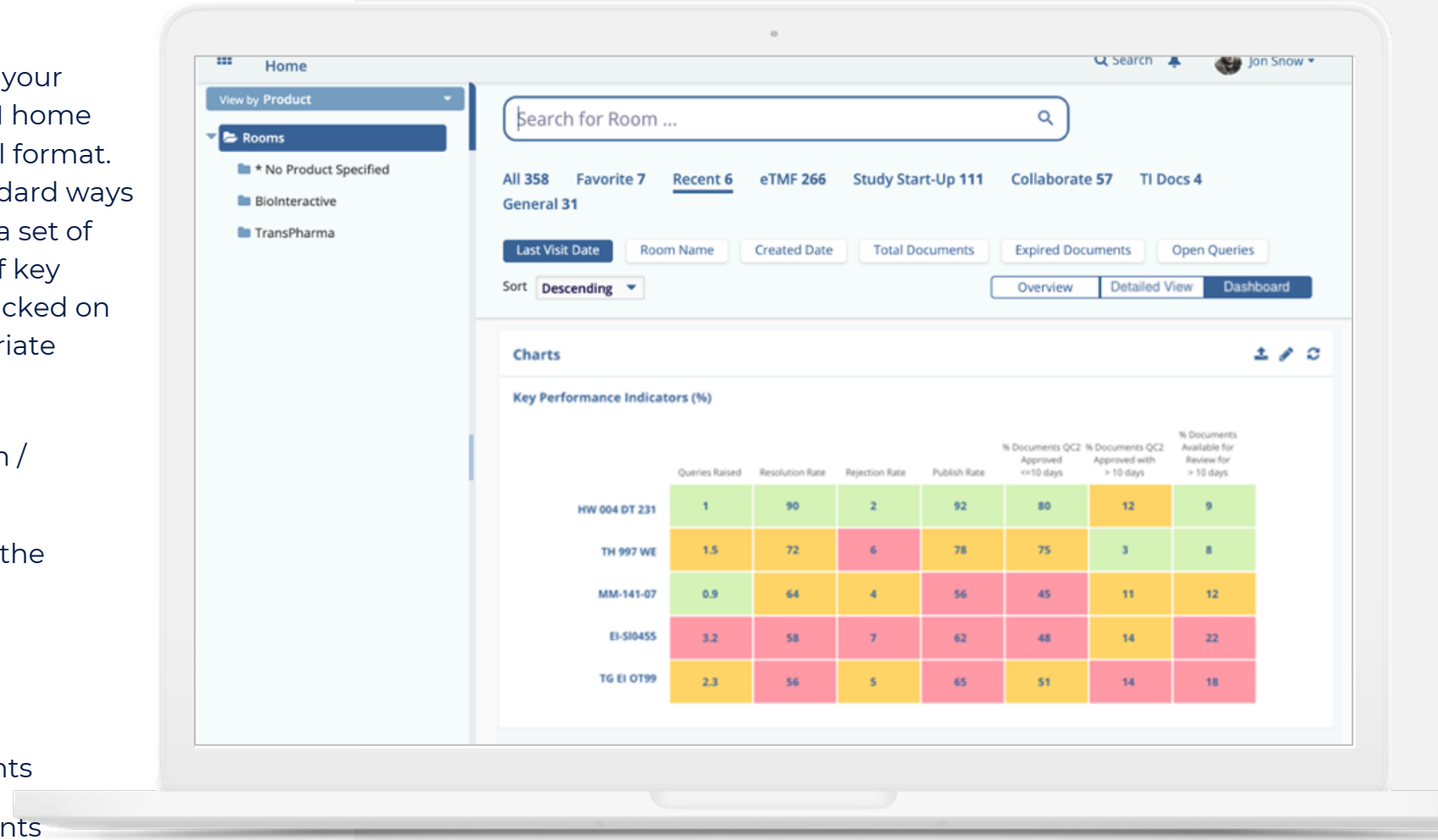
10.1.1 Dashboards

Portfolio Dashboards

In 10.1 Portfolio Dashboards are introduced for your organization, providing a third option on the TI home page that show the filtered results in graphical format. Rooms and studies may be filtered in the standard ways on this page and will show the dashboards as a set of definable metrics, with colors based on a set of key performance thresholds. All metrics may be clicked on to take the current user directly to the appropriate study room and view for more information.

View the following information by organization / submitters:

- % of Documents Published / Submitted in the Period
- % of Documents Published in n days
- % of Documents Not Published in n days
- Clarifications as a % of Published Documents
- Clarifications as a % of Submitted Documents
- Rejections as a % of Submitted Documents
- Rejections as a % of Reviewed Documents

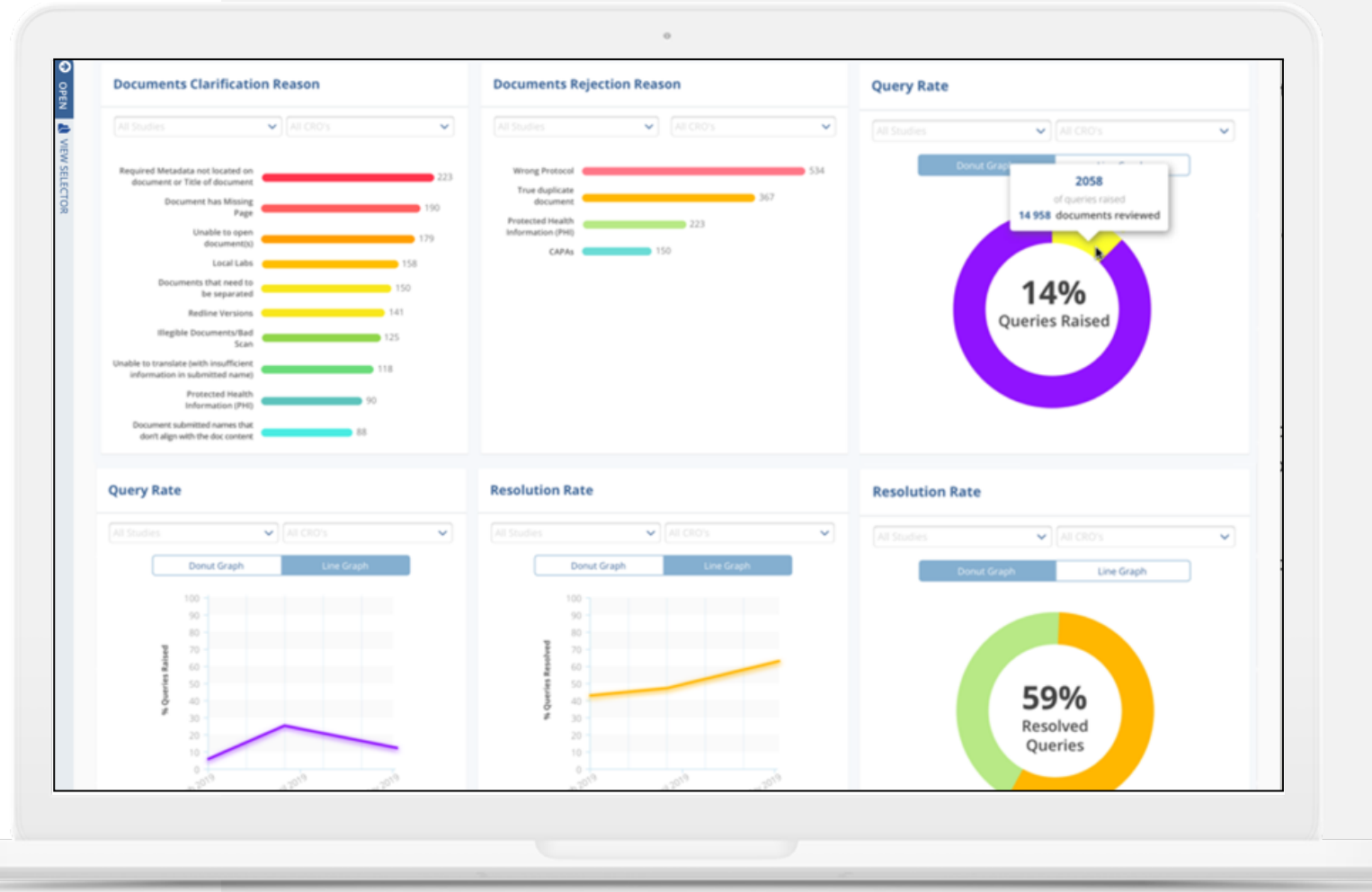


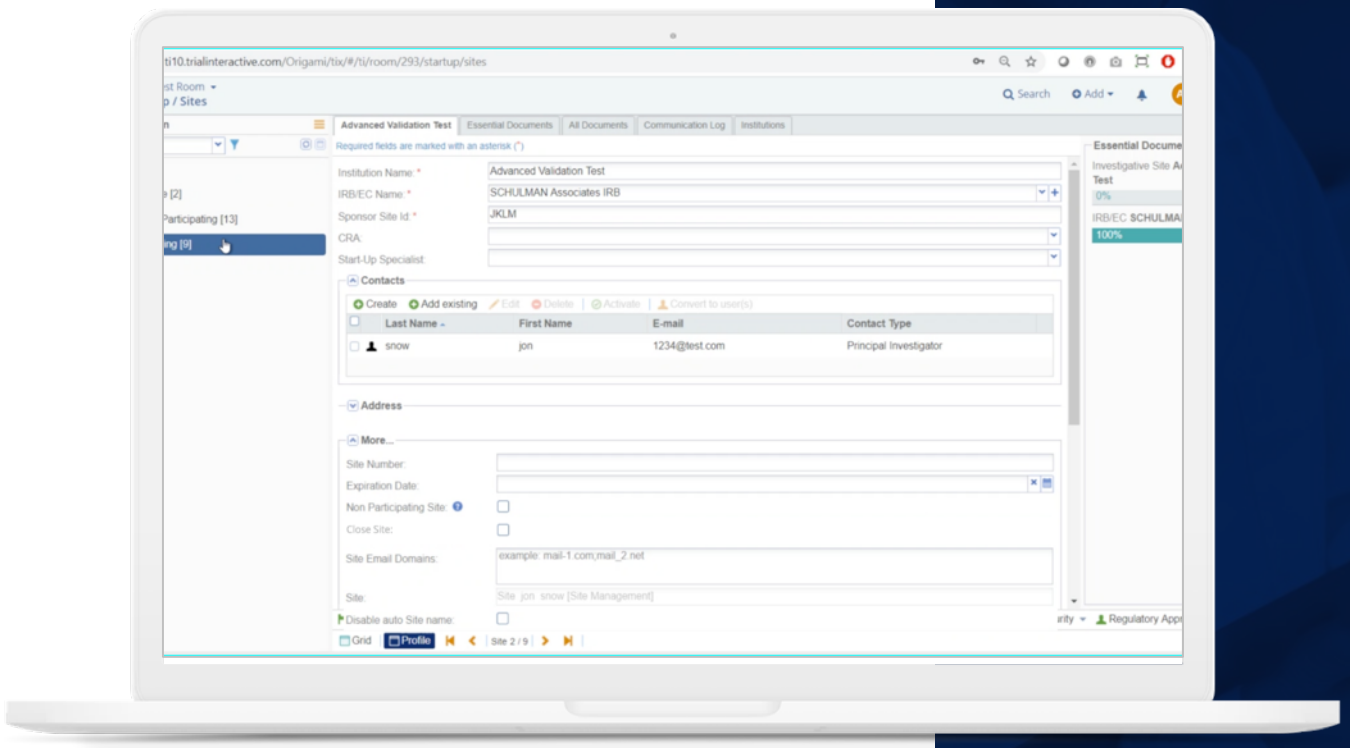
10.1.1 Dashboards

KPI Dashlets

10.1 introduces key performance indicator (KPI) dashlets, which are a set of standard dashlets that let you look at eTMF metrics across multiple studies. They provide a way to configure your measurements against thresholds and confirm issues, and view trends in completeness, timeliness, quality, and processing times across quality checks and by study, CRO, and submitter. These dashlets include:

- Document Timeliness from Document Date to Submitted, QC1, QC2, and Final.
- Number of Documents Submitted
- Number of Documents Published
- Number of Documents Rejected
- Number of Queries Raised
- Number of Pending Queries
- Number of In-Progress Queries
- Number of Documents Available for Review
- Number of documents available for review for >n days
- % of all documents in the system for > n days (includes all documents)





10.1 STUDY START UP UPDATES

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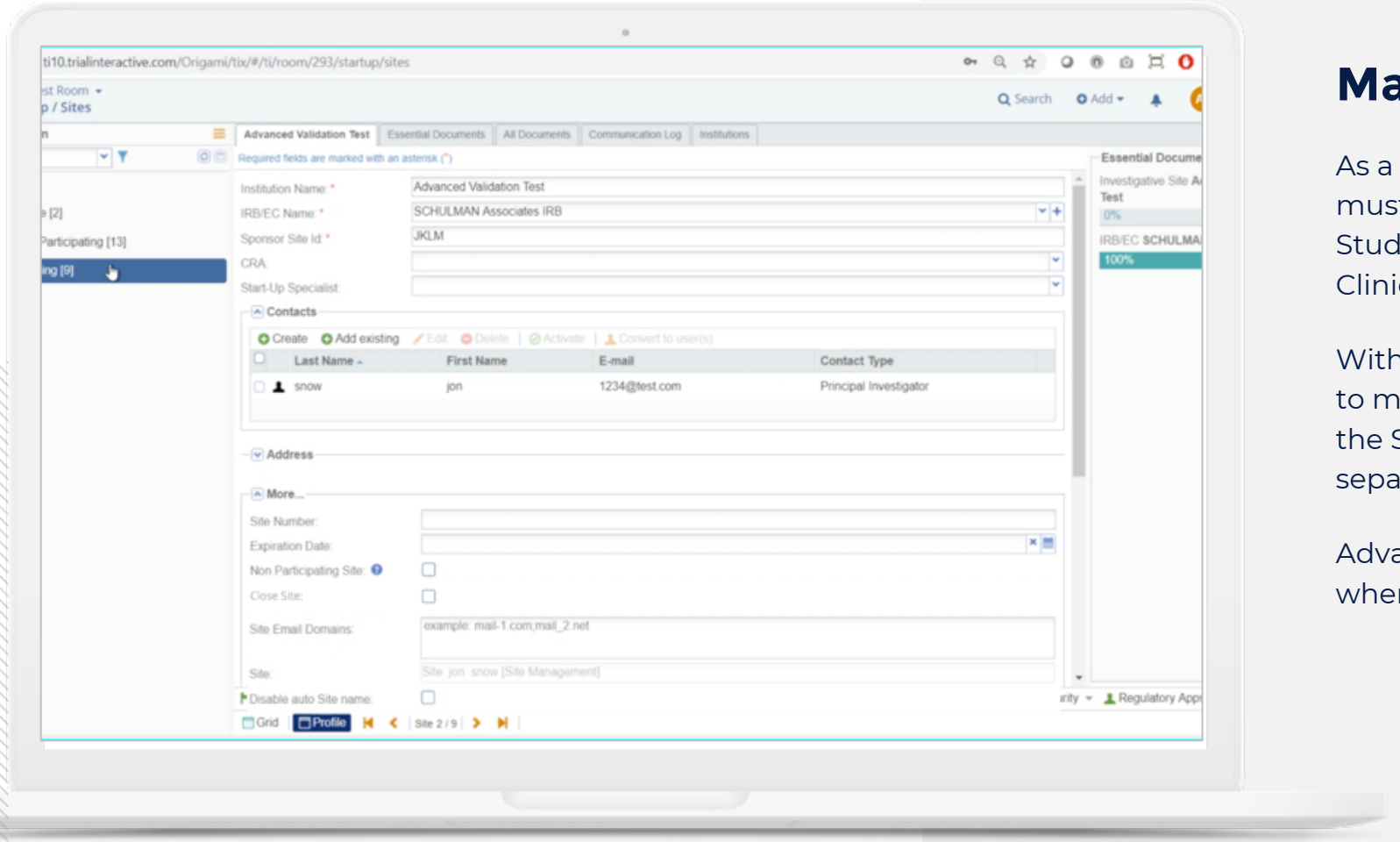
Site Closed Status



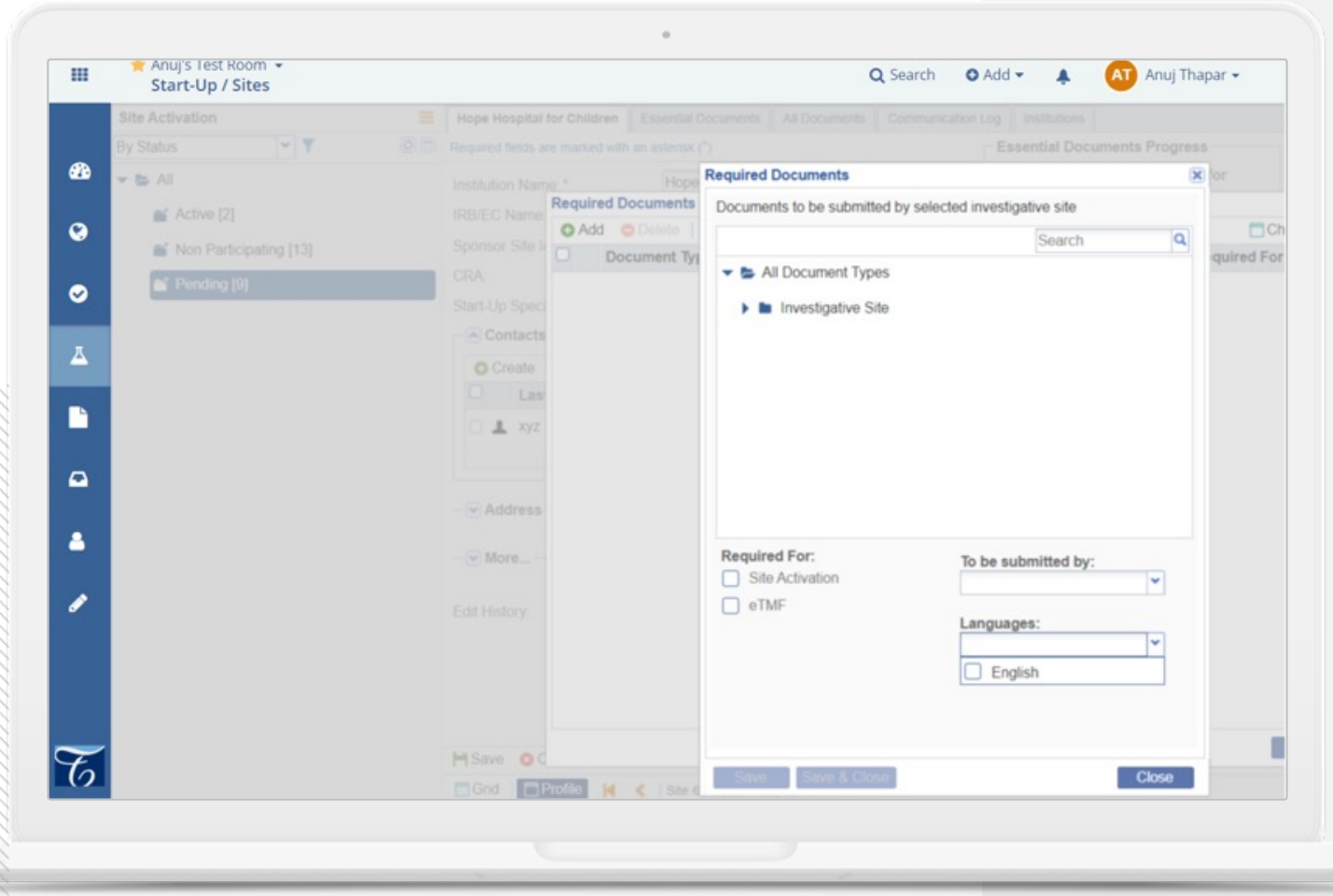
Marking Sites As Closed

As a Clinical Trial is completing, the investigative Sites must ultimately be closed. While not typically part of Study Start Up, this process is very much a part of the Clinical Trial lifecycle.

With Trial Interactive 10.1 the system shall have the ability to mark Sites as closed once the trials are completed for the Sites. Once closed, these Sites will be moved to a separate folder for closed sites.

Advanced Validation for metadata fields is still available when Sites are marked as Closed.

Essential Document Multiple Times



Support for Multiple Translations and Multiple IRB/EC Approvals

Quite often, the same Document Type requires a translated version, for example a regulatory authority may require the document in French, German, and English.

Additionally, there may be multiple IRB/ECs required in the regulatory approval workflow, and so the same Document Type may need to be recorded for each of these separate organizations.

For this reason, in SSU 10.1 a document type may now be set up as required document multiple times. They can now be setup as required documents more than once based on:

- Language
- IRB/EC

This improves support for European agencies, as well as supporting the process where more than one Ethics Committee may be required for a specific Country or Site's activation.

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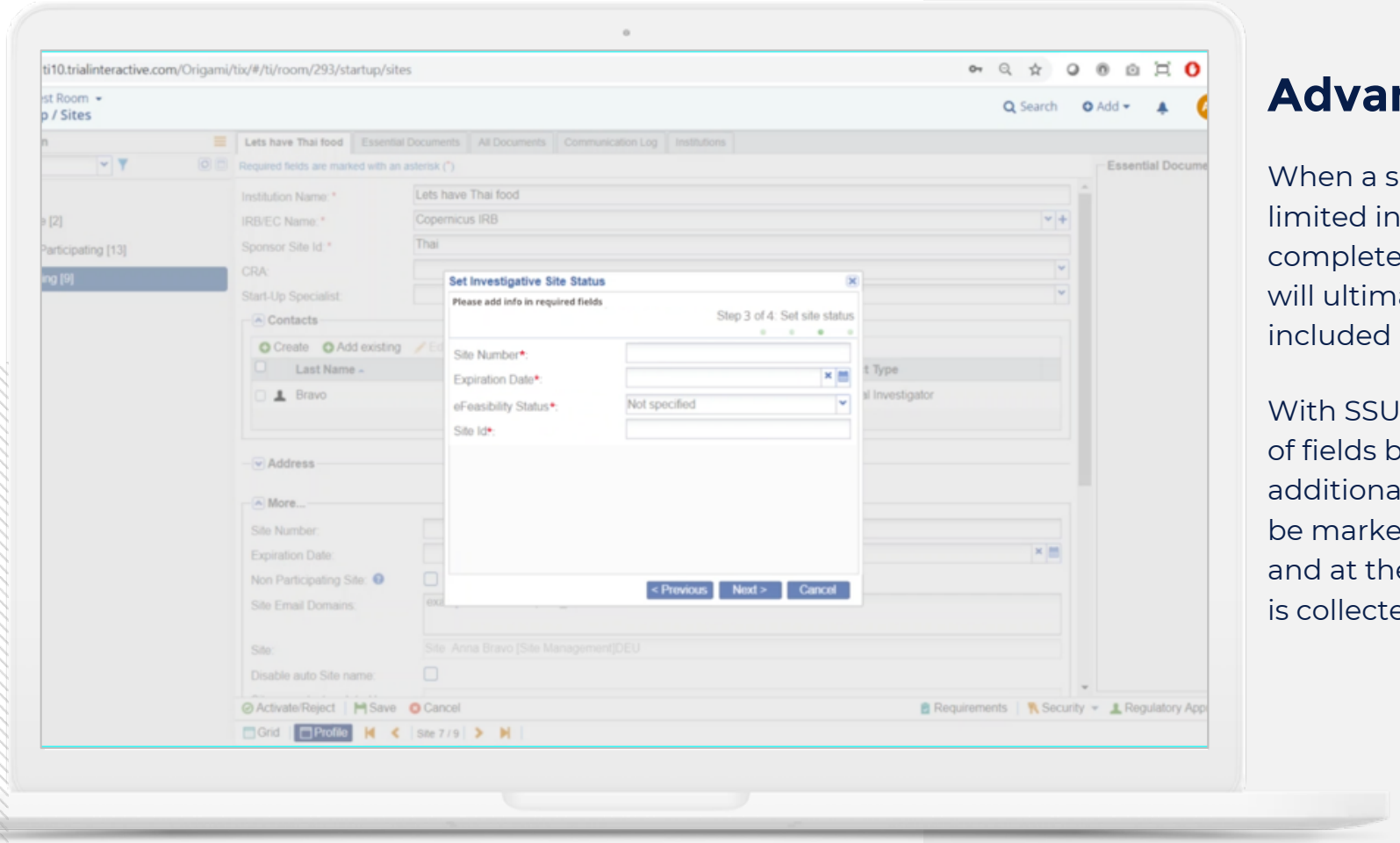
Site Activation Advanced Validation

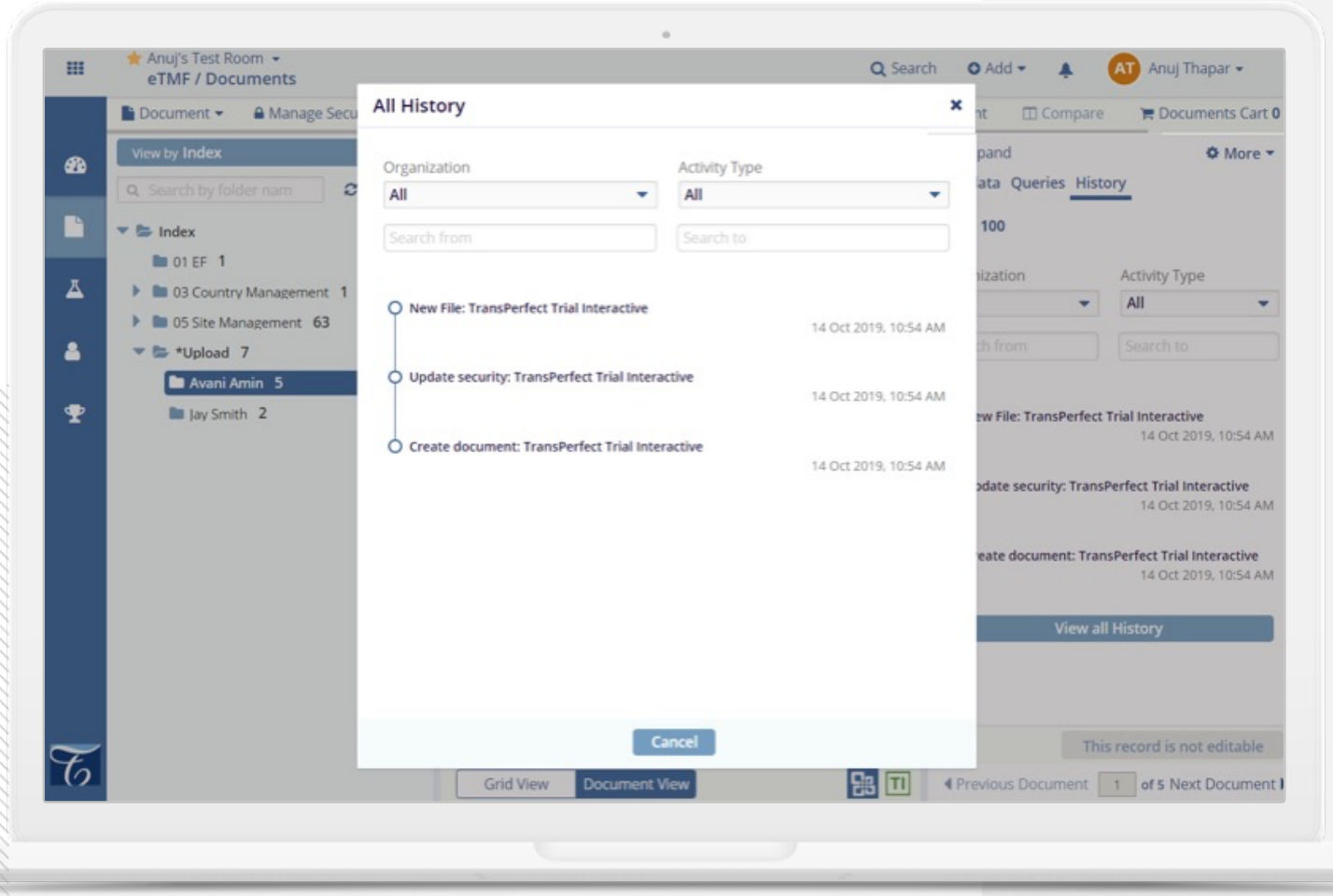


Advanced Validation

When a site is created the Sponsor/CRO may have only limited information about the site, and often cannot complete all the required fields. However, the Sponsor/CRO will ultimately gather more information that must be included before the Site can be marked Active.

With SSU 10.1, Sites can now be configured to require a set of fields be filled out with initial site creation and require additional fields that must be filled out before the site can be marked Active. This allows a simplified creation process, and at the same time ensures that all required information is collected prior to the Investigative Site going live.

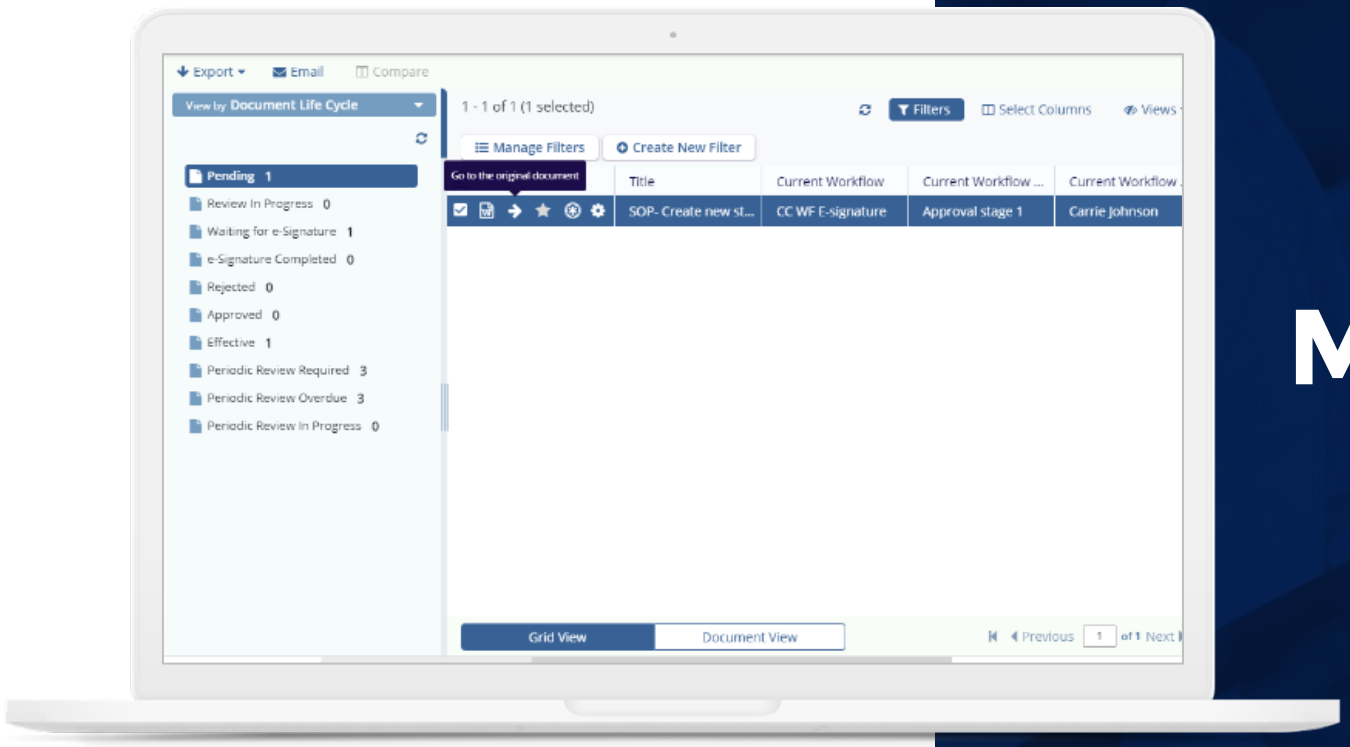
SSU Document History



Document History

During the course of Study Startup, Documents must go through a standard process before they are considered approved. With SSU 10.1, Users now have the ability to view the complete history of the documents in SSU. This includes:

- Submitted By
- Submitted Date
- Start-up Specialist Approver
- Start-up Specialist Approval Date
- Regulatory Reviewer
- Regulatory Approval Date



10.1 CONTENT MANAGEMENT UPDATES

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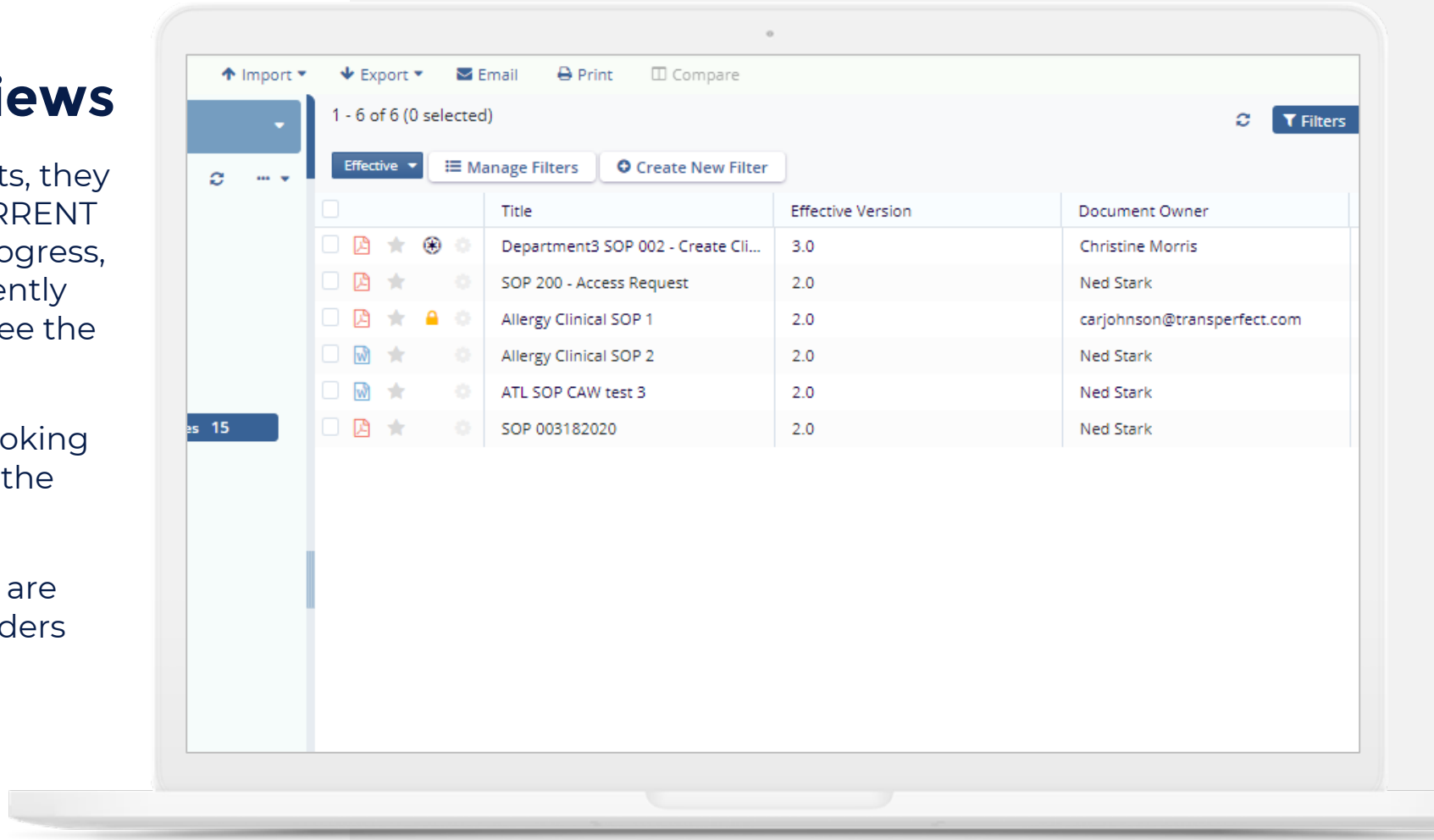
TI 10.1 Content View

Role-Based Content Views

When Editors are looking for documents, they always want to see the latest, most CURRENT draft version, so they know what's in progress, what needs reviewed, and what is currently approved and effective. They want to see the latest edits.

Conversely, when casual Readers are looking at documents, they always want to see the current, EFFECTIVE version.

In 10.1, the TI CMS will provide views are are most logical for each role, showing Readers the EFFECTIVE version, and Editors the CURRENT version.



TI 10.1 Content View

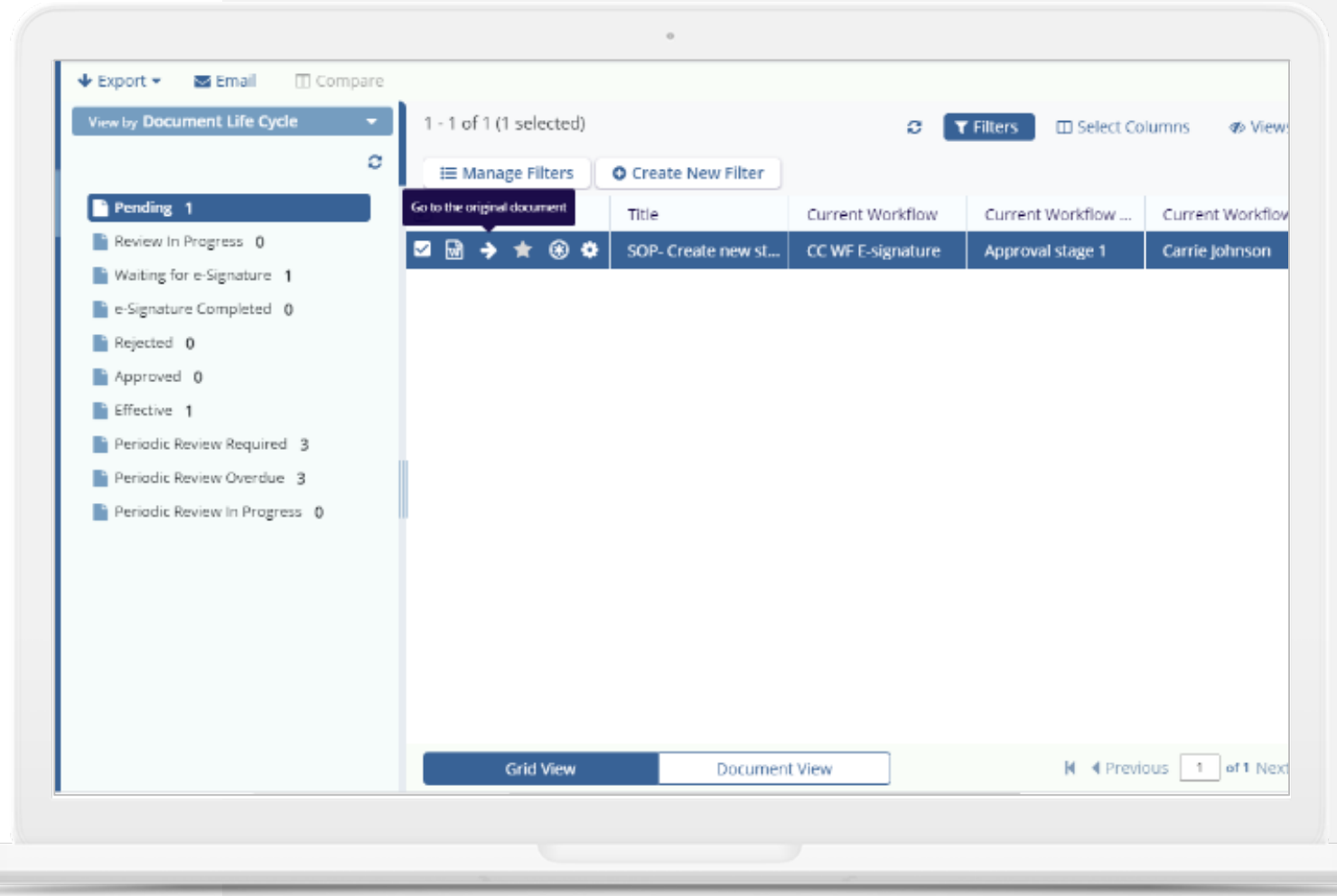
Improved Workspace Navigation

Now users can easily navigate between the Document Repository and Collaborative workspace or Document Lifecycle for a single document.

Within the Document Repository users can click on the collaborative icon to take them to that document in the Collaborative workspace. Users can click on the workflow icon to go directly to the document and its status in the Document Lifecycle.

Within the Collaborative workspace click on the right facing arrow on the document row to view the document in its folder in the document repository.

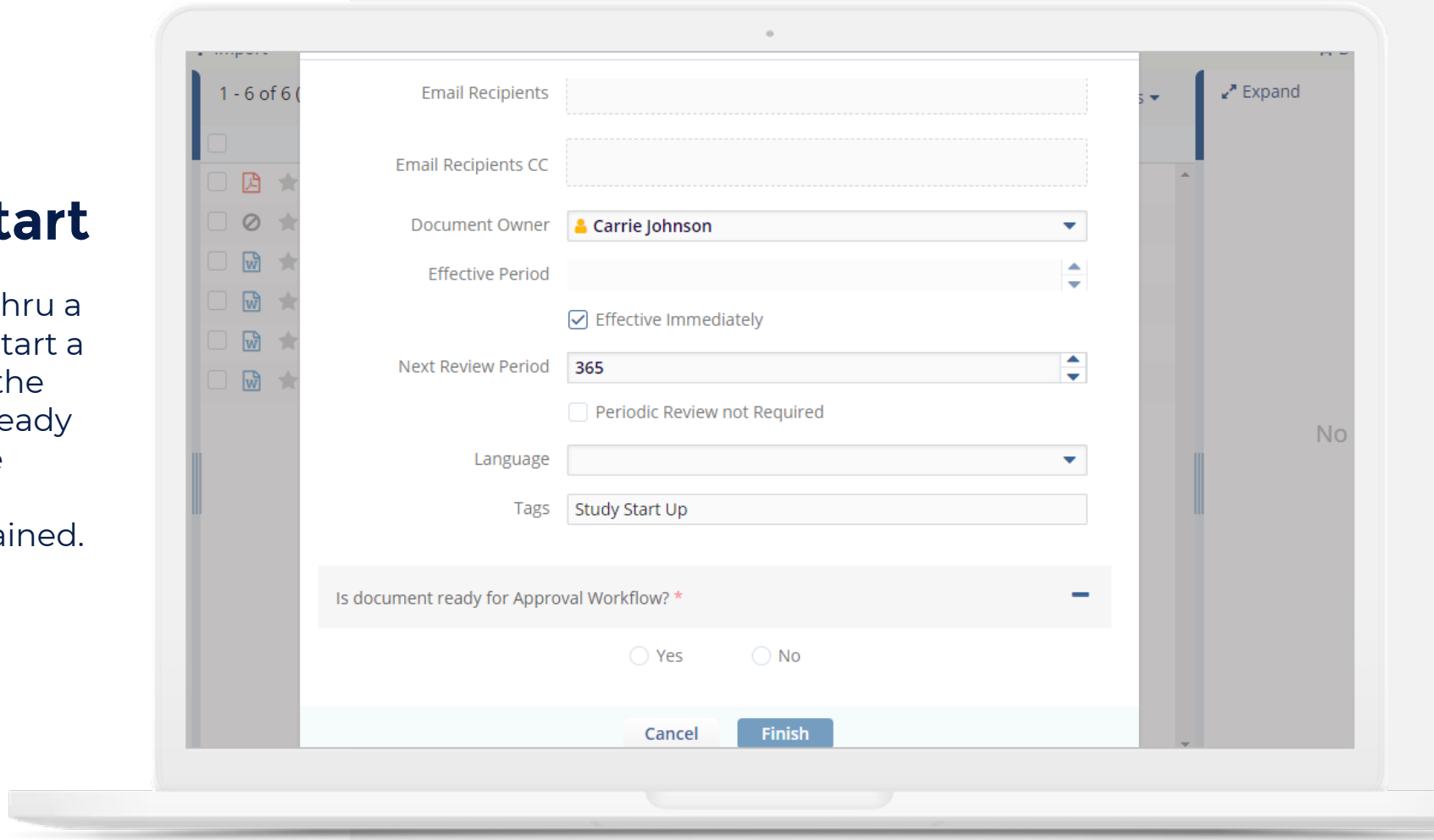
Within the Collaborative workspace click on the right facing arrow on the document row to view the document in its folder in the document repository.



TI 10.1 Workflow

Simplified Workflow Start

No longer will a document need to go thru a round of editing prior to being able to start a workflow. With CMS 10.1, upon upload the user will be able to set a document as ready for a workflow and the workflow can be initiated right after save. Immediate approvals and E-signatures can be obtained.

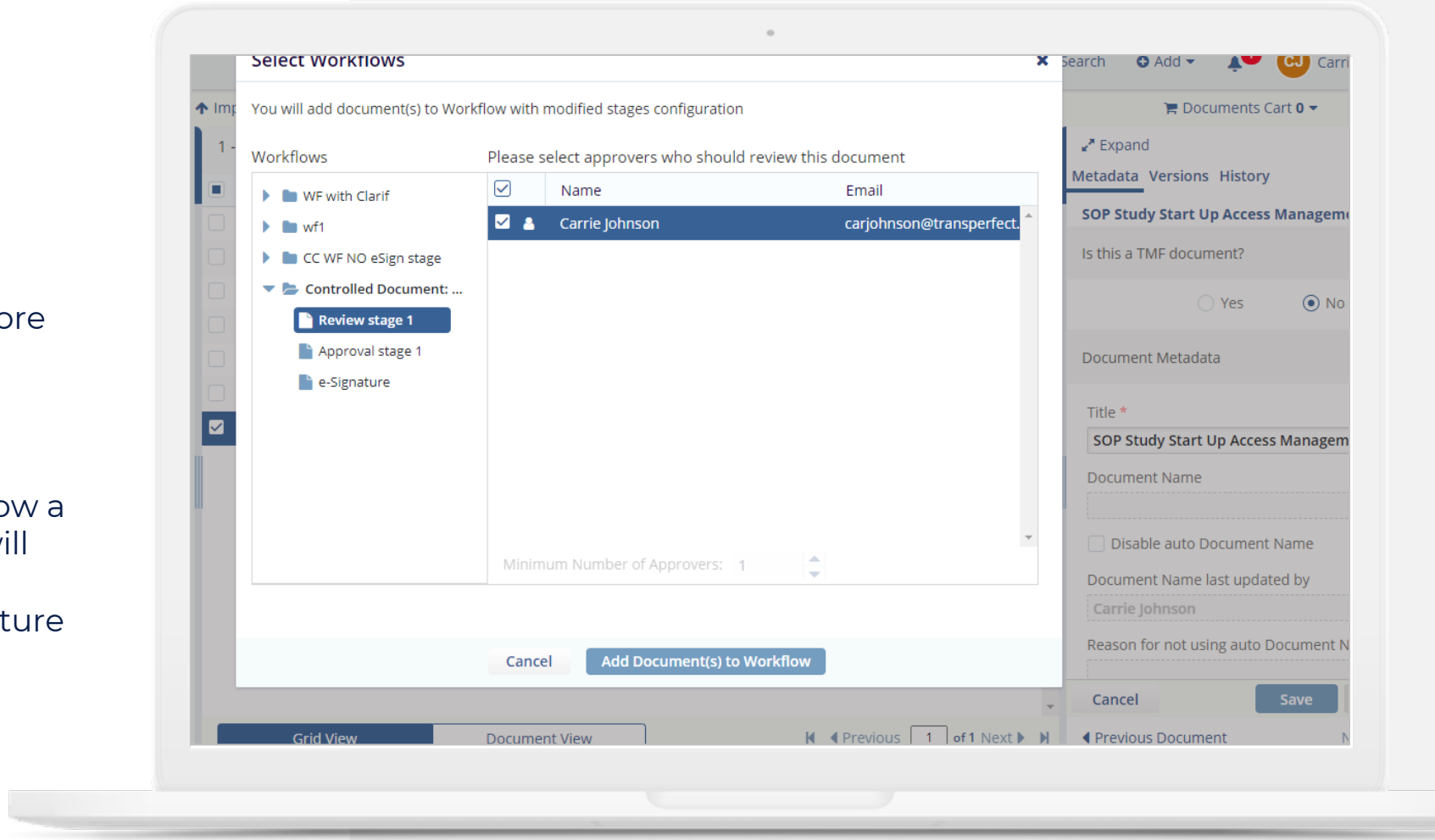


TI 10.1 Workflow

Collaborate Within a Controlled Document Workflow

In CMS 10.1, Document Owners have more workflow choices for their Controlled document.

Workflows can be created for business needs providing review steps which allow a document edit, approval steps which will provide an approval event in the document history as well as an E-Signature step to obtain signatures on the document.



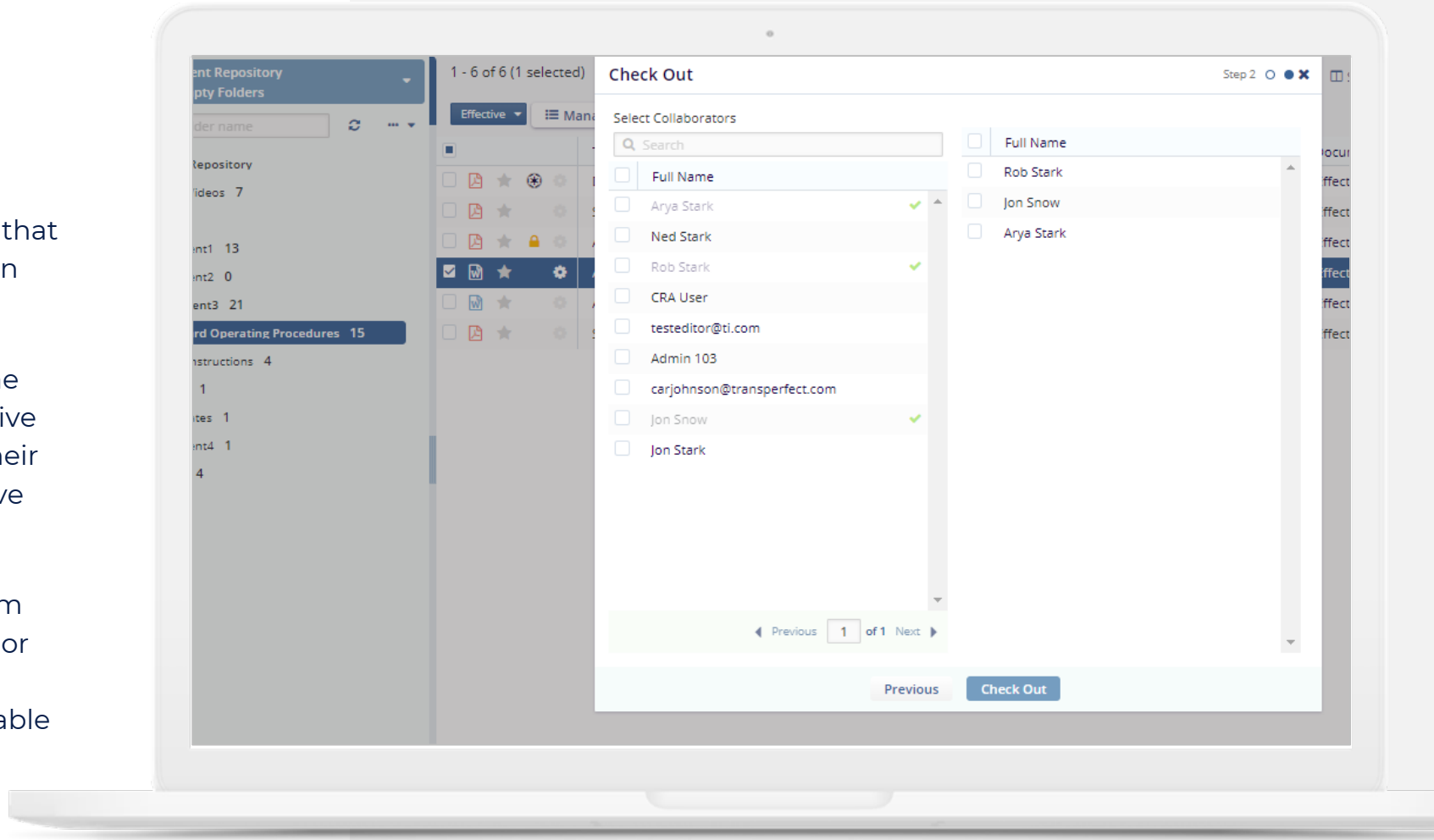
TI 10.1 Workflow

Collaborate with Users Outside Workflow

This improvement will allow document collaboration to occur with room participants that may not have direct access to the document in the document repository.

Documents can be managed in a folder by one set of users and then as needed for collaborative review new distinct user can be invited and their edits controlled to only during the collaborative review.

This will provide an easy way to gain input from subject matter experts, outside organizations or other departments in a controlled timeframe without leaving the document open and editable for all the editors at all time.



TI 10.1 Document Control

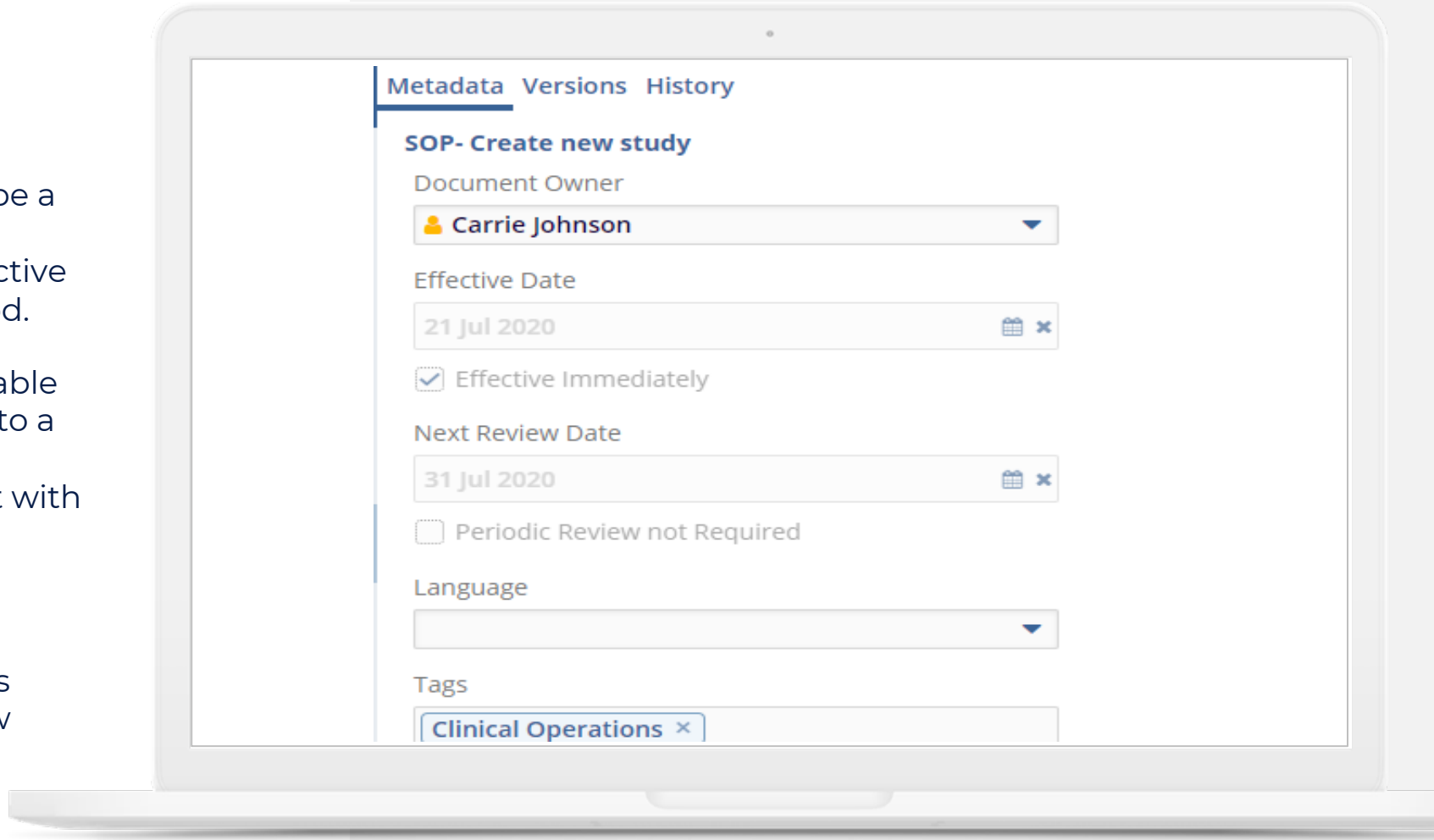
Flexible Controlled Document States

For Controlled Documents, there may be a need to make a document Effective immediately or make a document Effective with or without a Periodic Review Period.

With 10.1, Document managers will be able to control what does or does not apply to a document providing ability to meet business requirement of the document with ease.

Document owners will be able to:

- Control the duration of a documents Effective Period and Periodic Review Period
- Set a document to be Effective immediately after approval with or without a Periodic review Period



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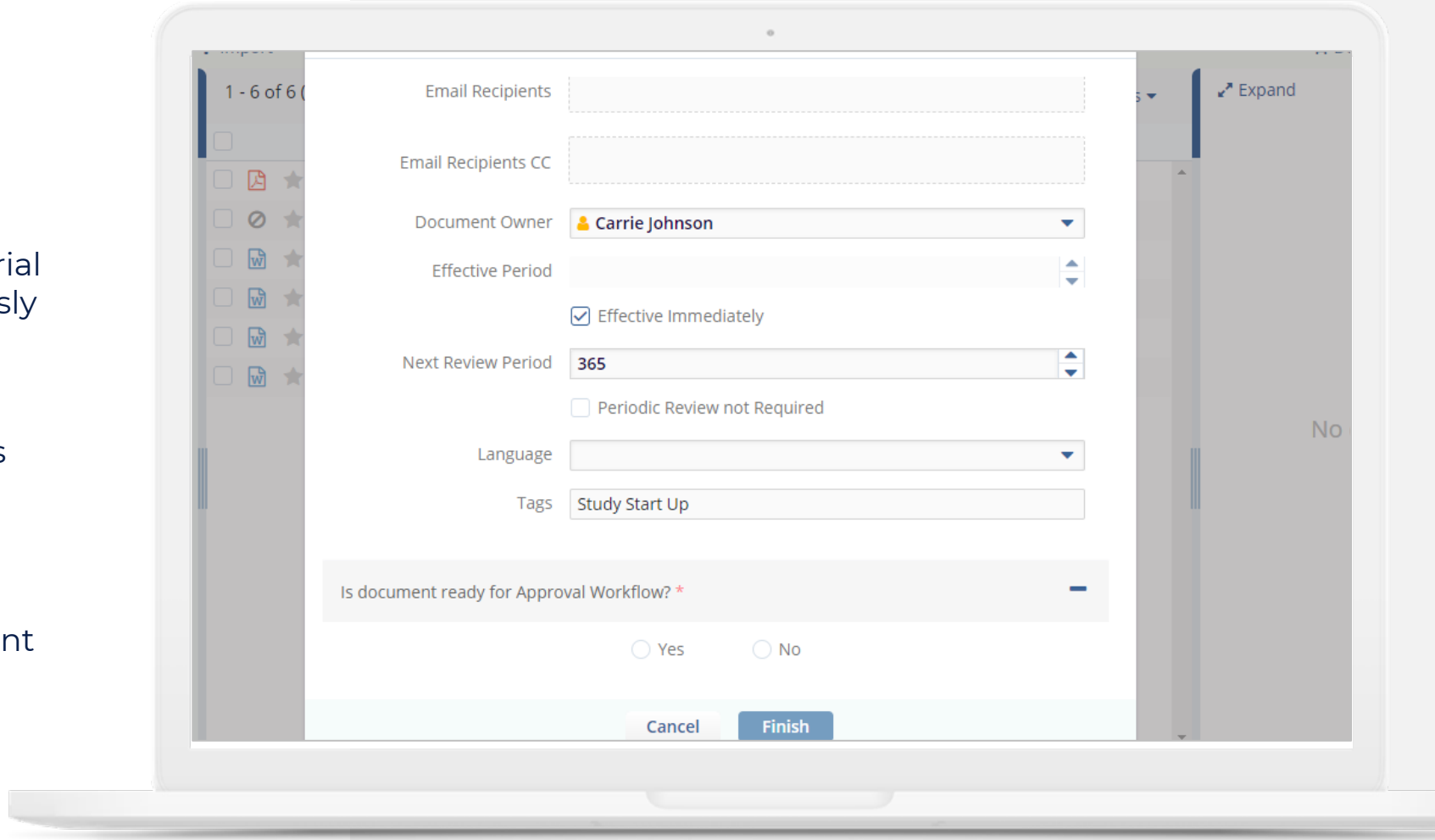
TI 10.1 Document Control

Version Labels

Upon document upload, users will be able to set the initial version in Trial Interactive allowing the document in Trial Interactive to be able to inherit previously defined versions.

Trial Interactive will allow for the initial version of a draft document to be set as 0.1.

The control of the document version labels will allow organizations to easily follow their own procedure for document management.

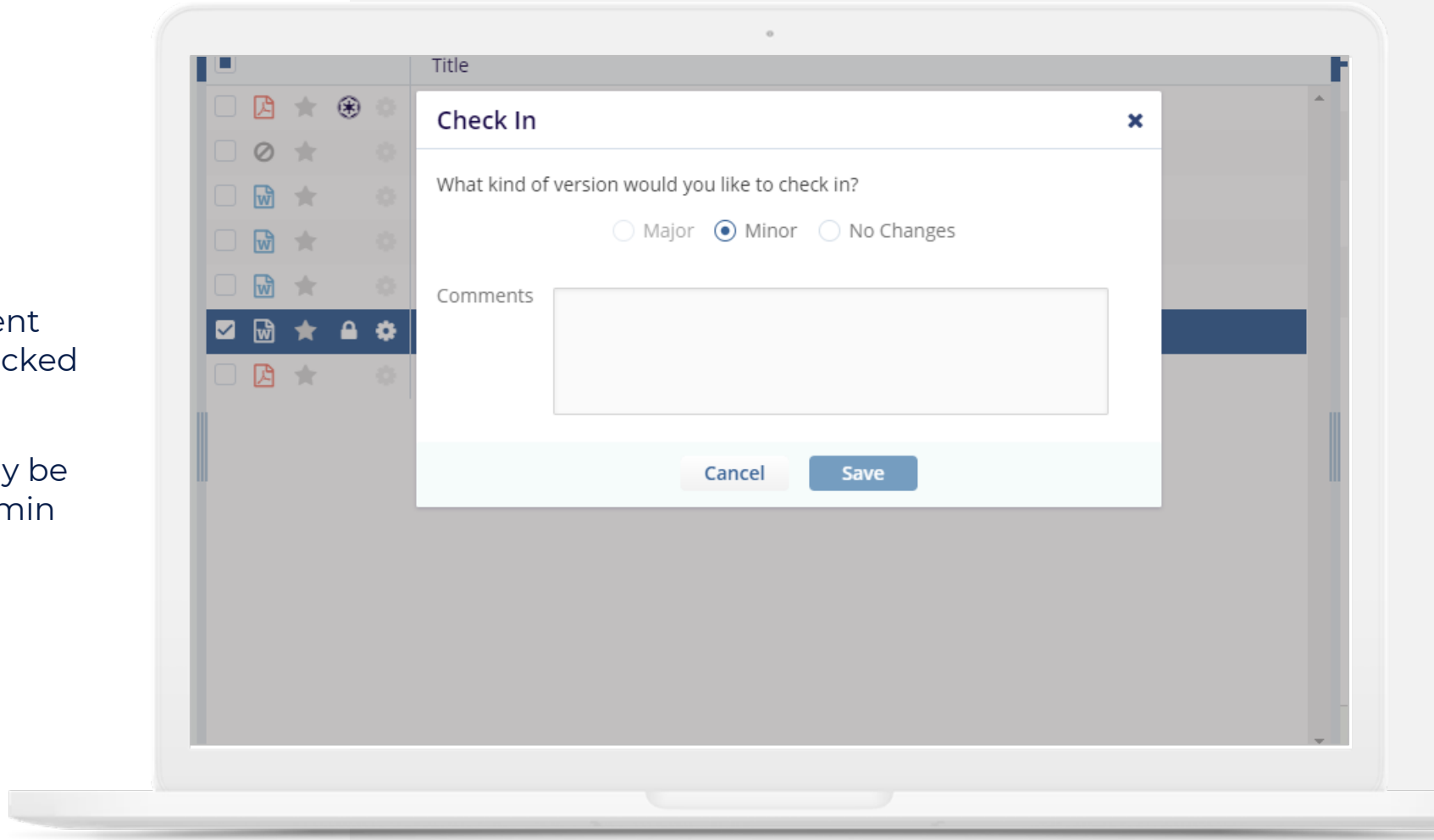


TI 10.1 Document Control

Cancel Check-out

This improvement will allow room administrators in a Content Management room to check back in a document checked out by another user.

In cases where a user may unexpectedly be unavailable or unresponsive a room admin can free up the document locked by a collaborative edit or an individual edit.



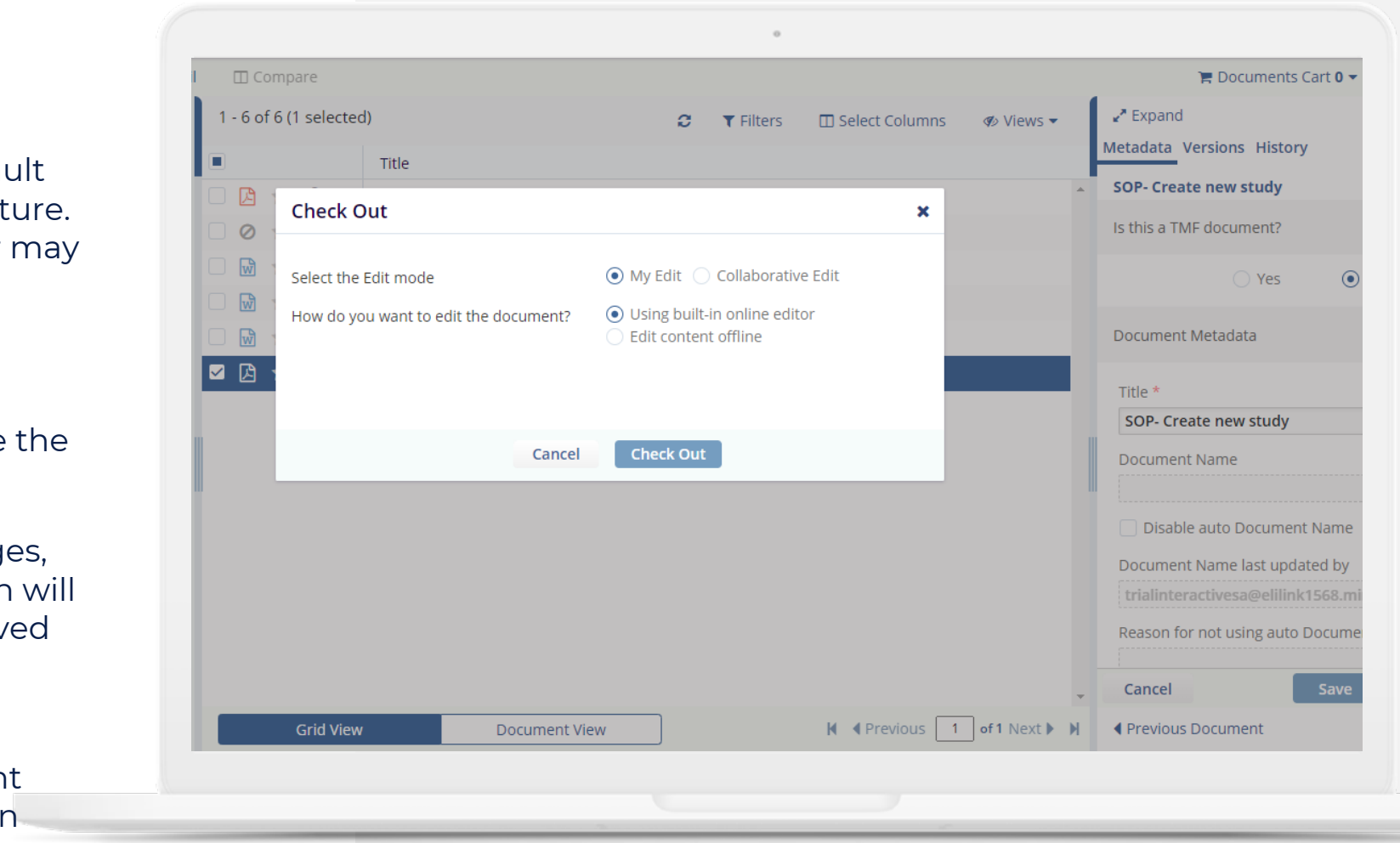
TI 10.1 Document Control

Simplified Check-out

With CMS 10.1, Users who check-out documents for editing will now by default use the online collaborative editing feature. Users may decide they will be offline or may need to use their local MSOffice™ application for editing a document. Selecting this option will now open the document in the local application automatically, allowing the user to save the document for offline editing.

Once they have completed their changes, they can check-in the document, which will prompt them to upload their locally saved version.

This change will simplify the options available to users. NOTE: Any document checked-out using the online editor can always be edited later in the native MSOffice™ format.



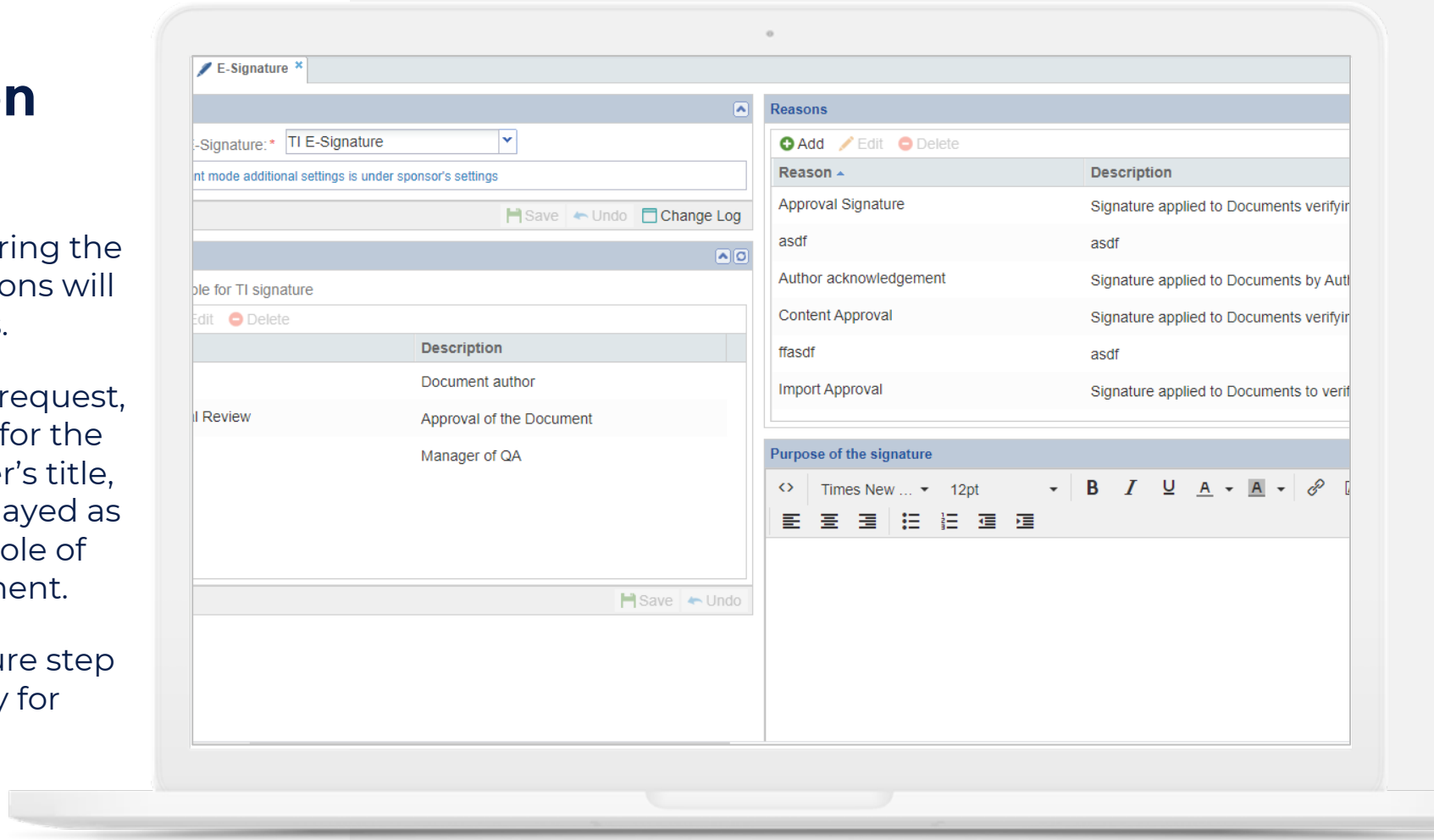
TI 10.1 TI Sign

TI Sign Title and Reason for Signature

Roles can be defined and leveraged during the E-Signature step. The standard definitions will create consistency across all signatures.

During the creation of the E-Signature request, each signer can be associated to a role for the document. This allows not only the user's title, and reason for the signature to be displayed as part of the E-Signature record but the role of the person in the lifecycle of the document.

Title and Role inclusion in the E-signature step provide high level of visibility and clarity for each signer of a controlled document.

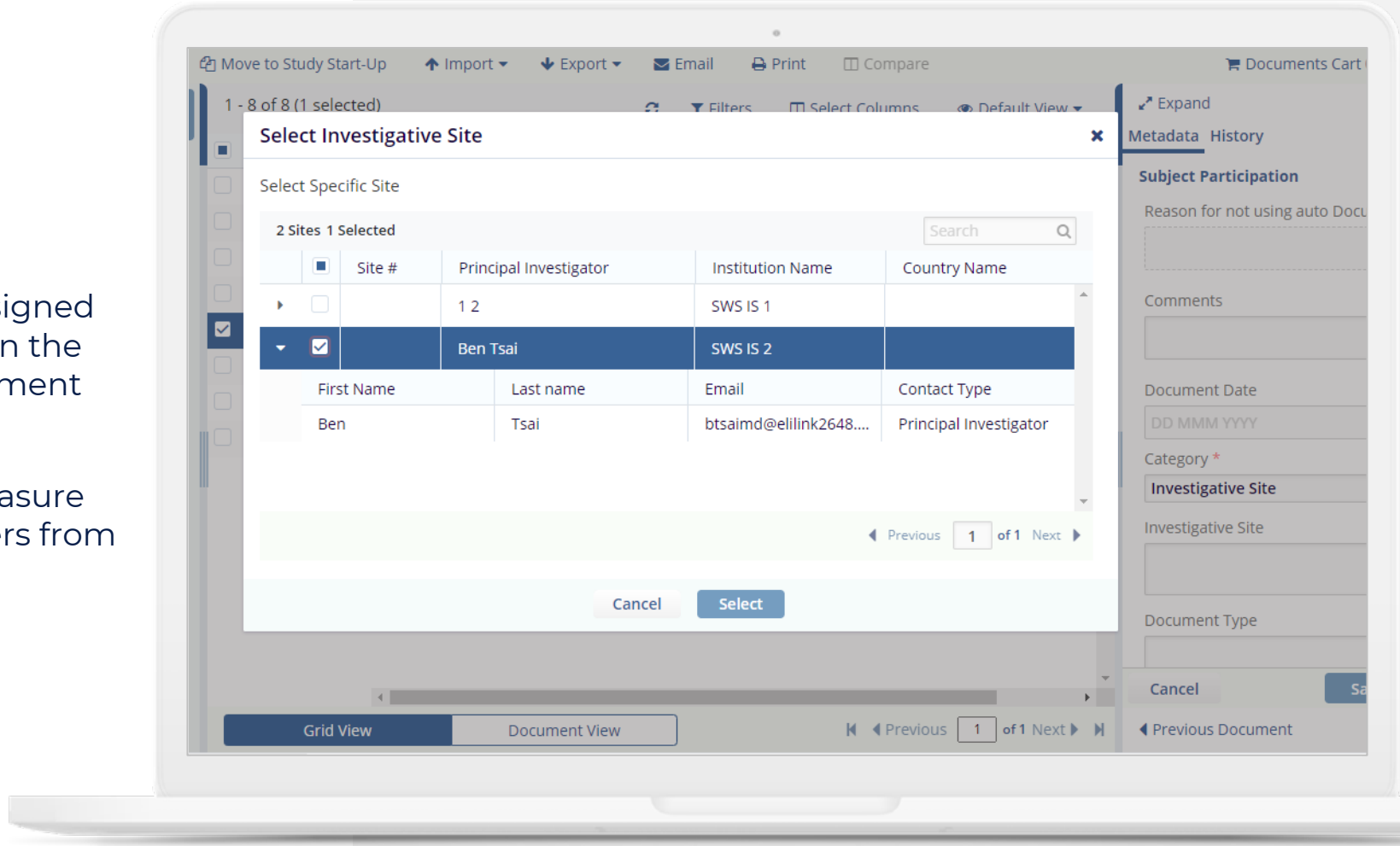


TI 10.1 Document Security

Site User Restrictions

This improvement will restrict users assigned to sites to only see their assigned sites in the Investigator site list when adding document or updating document metadata.

This provides an additional security measure eliminating other site names or numbers from site specific users.



TRIAL INTERACTIVE

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