



Mid-Study Transition of a Global Study: Migration from Paper TMF to eTMF

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TransPerfect- Trial Interactive
OCTOBER 23, 2013

AGENDA

- Scope of Project
- Initial Steps
- Execution
- Challenges & Resolution

CLIENT NARRATIVE

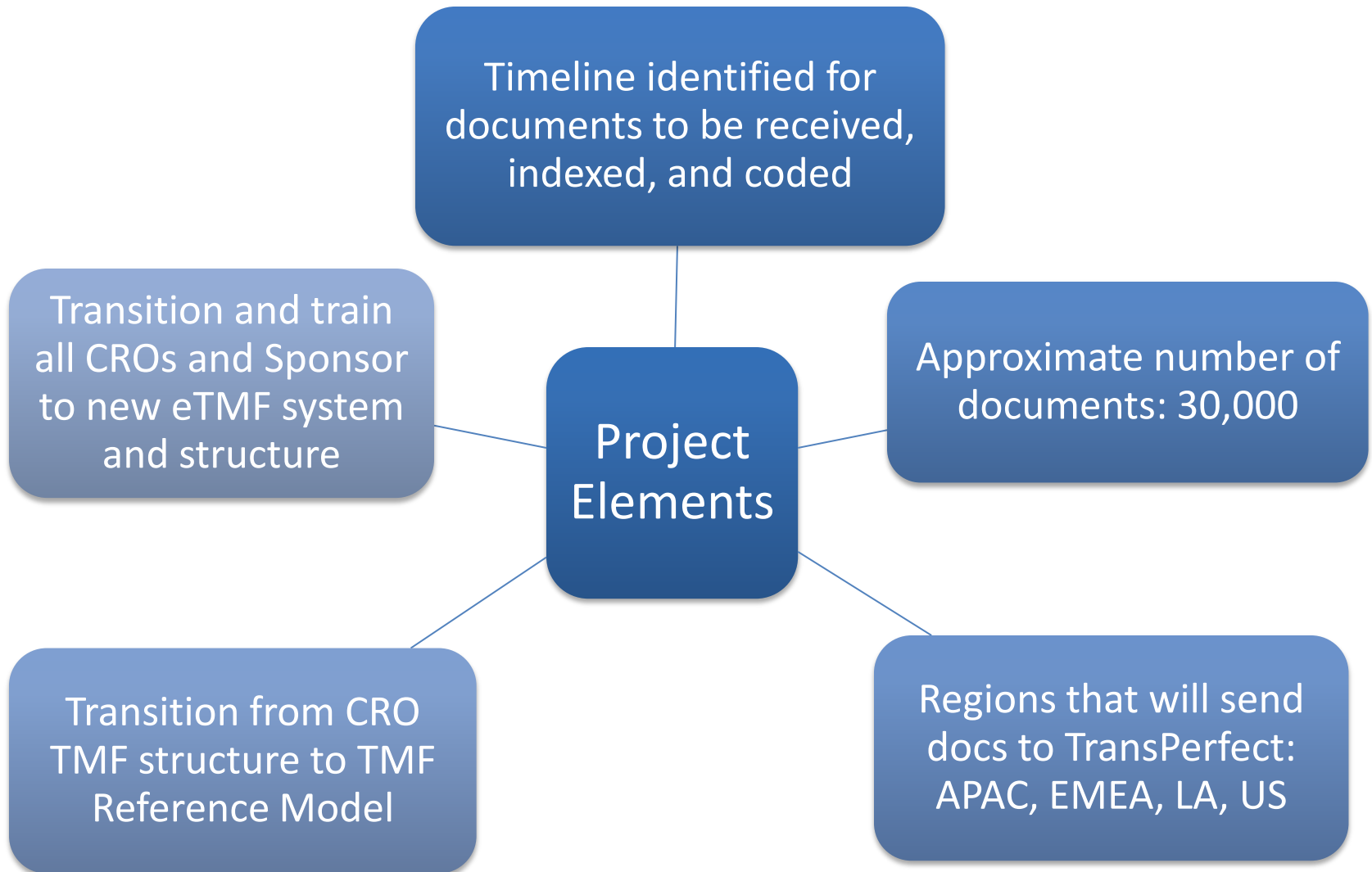
Client: Major Pharmaceutical Company conducting a Phase III study in 30 different countries

- Initially started using only one CRO as primary TMF holder
- Planned to expand to additional countries around the world
- Hired three additional CROs regionally
- Initiated the transfer of TMF during the study start up process

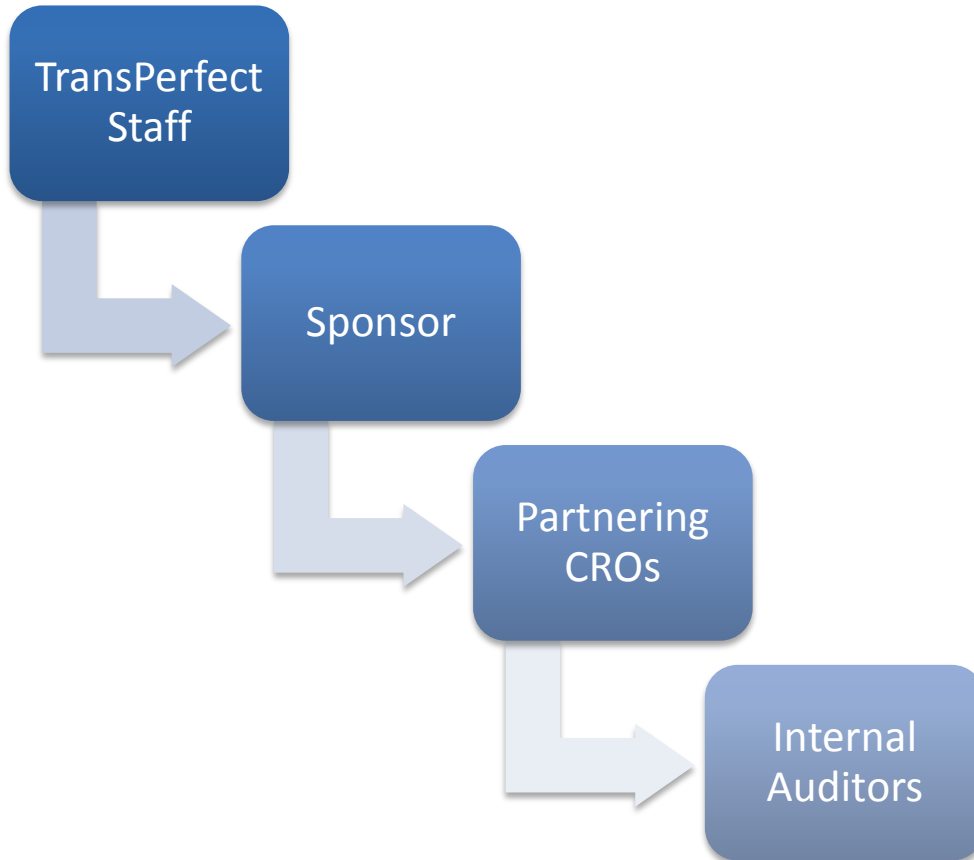
Site Activation

- Goal of 400 sites world wide
- At the point of transfer 120 sites were active within 30 countries

SCOPE OF PROJECT



INITIAL STEPS: TRAINING



INITIAL STEPS: SET UP

Set-up index structure and confirm specifications of metadata to be collected

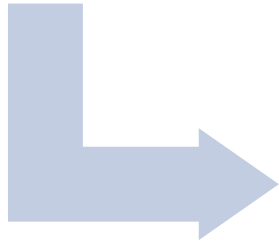
Generation of configuration and mapping document

Generation of document transmittal form

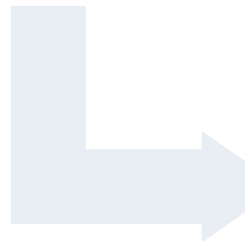
Highlighting specification on document submission (wet ink, translation required)

INITIAL STEPS: TIMELINES

Set timelines for receipt of paper documents, inventory, scan, upload and index of documents



Stagger timelines for site level versus central file documents



Generate document tracking reports to communicate transition progress

PROCESS EXECUTION

INDEXING

- Document transitional process of previous index structure to new index structure and share with client
- Mapping changes from the old index structure to the new

REPORTING

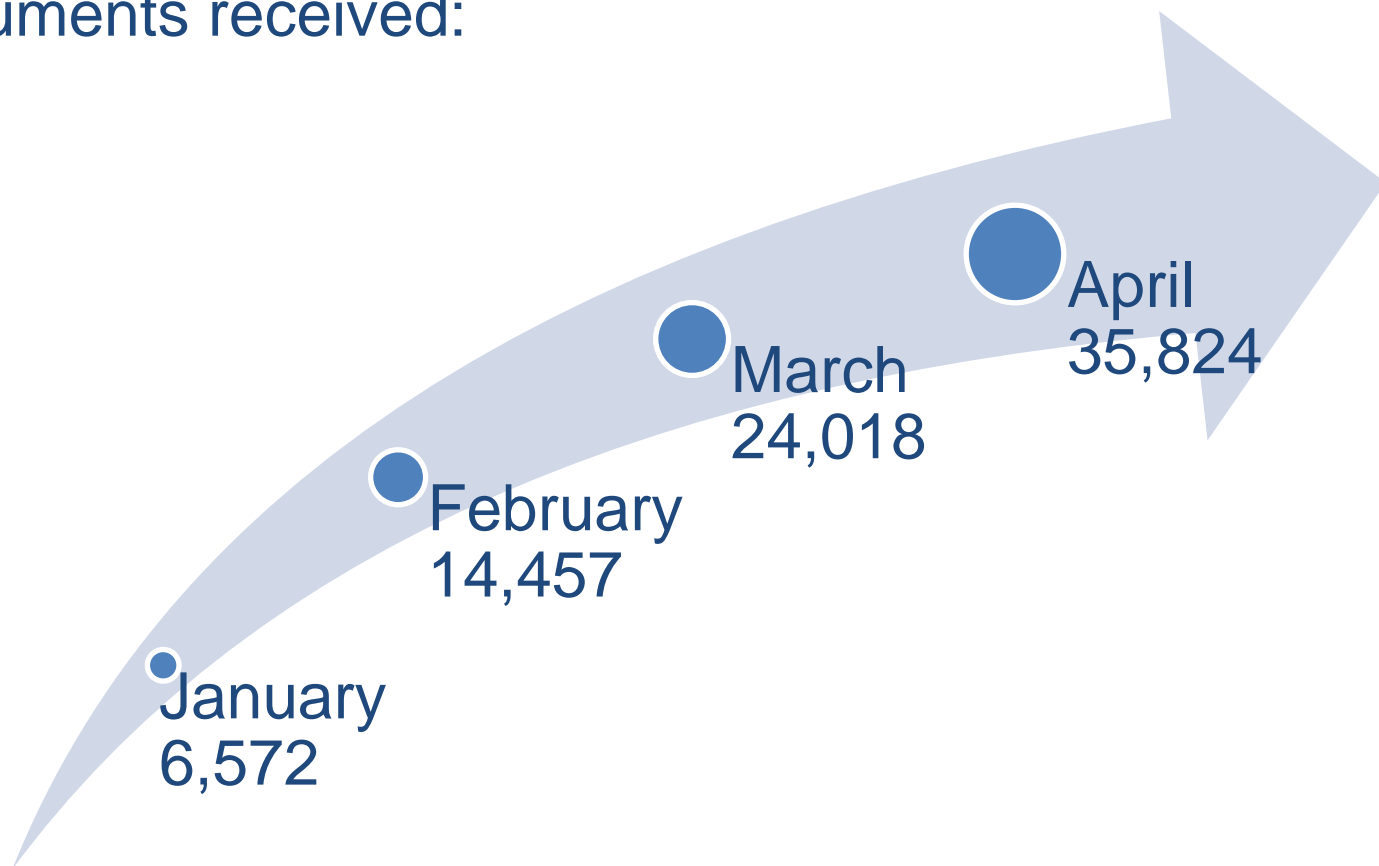
- Develop reporting mechanism for illegible documents and documents that need to be resubmitted
- Standardization of receipt documentation for multiple submitters

EXECUTION

- Track priority countries and priority site document
- Inventory, assign document ID, scan, and code document
- Streamlined indexing operation in the US and UK
- Streamlined coding process in India, US, and UK

EXECUTION: TIMELINE

- Documents received:



EXECUTION

- All documents coded and indexed by end of May 2013
- Initiate a reconciliation process with paper files to ensure accuracy and completeness of paper files
 - Reconciliation set to be complete by November 2013

CHALLENGES

- Multiple languages
 - Resolution: Translation
 - Upgrade: Inline translation of documents during coding process to increase efficiency

CHALLENGES

- Multiple changes to the index structure – the site file and country level filing structure
 - Resolution: File sign off on document mapping

SUMMARY

- Reduction in paper documents sent to eTMF
- Increased ability for reporting across all countries
 - Increased visibility on study metrics

CONTACT INFORMATION

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The background of the slide is an abstract, layered geometric pattern. It consists of various shades of blue and white, forming a complex, interconnected network of lines and shapes that resemble a molecular or cellular structure. The pattern is dense and fills the entire frame.

THANK YOU!