End of Study Transfer – Ensuring data integrity

Marion Mays, Sr. VP Clinical of Kivo
Toban Zolman, CEO of Kivo

Meet the Speakers

Marion Mays

Title: Sr. Vice President of Clinical

Organization: Kivo

Marion has over 30 years of experience supporting organizations through clinical trials and inspection with FDA, MHRA, EMA, and PMDA. Her experience working for sponsors, CROs, software vendors and directly helping sponsors manage inspections make Marion uniquely positioned to offer valuable insights into this process.

Toban Zolman

Title: CEO of Kivo

Organization: Kivo

Toban has extensive experience solving complex business challenges using software. He has worked with dozens of the largest global pharmaceutical companies to define business processes around clinical and regulatory processes. Toban is CEO of Kivo, a software provider focused on streamlining the drug development process for emerging life science **companies.**

Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

- *The author(s) have no real or apparent conflicts of interest to report.*

Agenda

1. End of Study Transfer Challenges
2. Kivo Case Study: 60 Days to transfer 25 studies
    1. People
    2. Process
    3. Technology
3. Lessons Learned
4. Looking to the Future

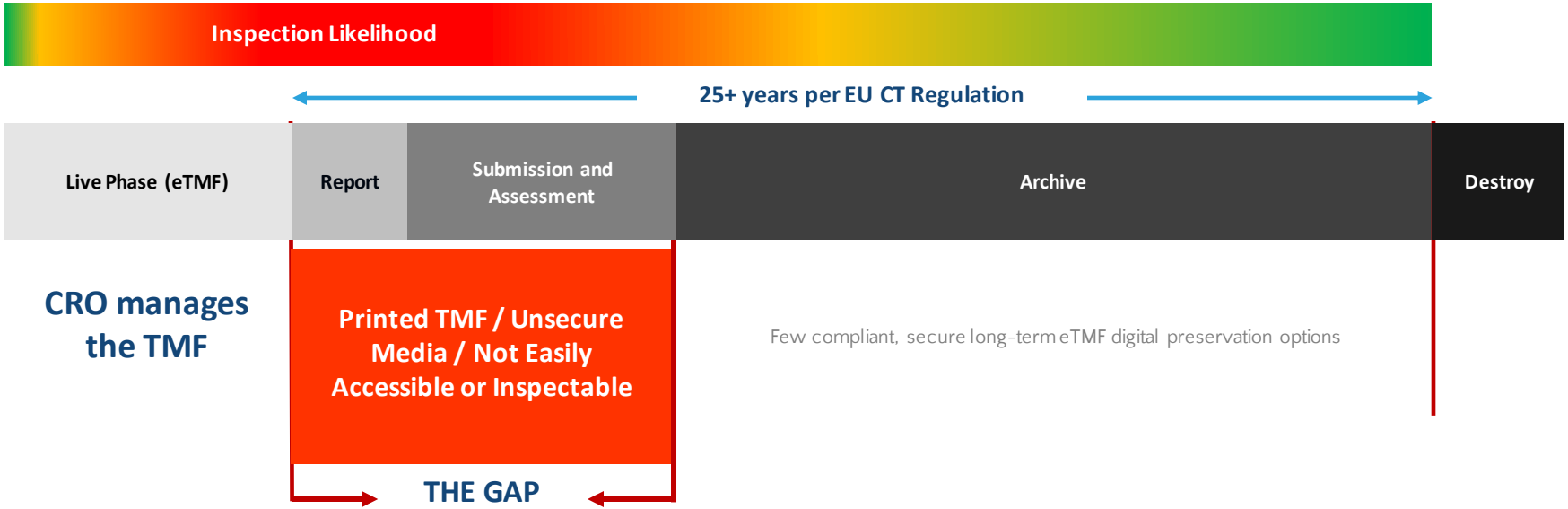
End of Study Transfer Challenges

Your Study has Closed – What's the Plan?

You collaborated with your CRO and they managed not just the study activities, but they also have all the documentation that holds the story of your study. As the sponsor, this is the evidence of how the study was conducted which means you need it for your regulatory approval and long-term archiving.

- Do you have an eTMF system?
- How are you managing and documenting the handover?
- What steps are you taking to ensure you have all your data and that the data is accessible for inspection in a controlled manner?
- Yes some of the studies are old, but will they still be inspected?

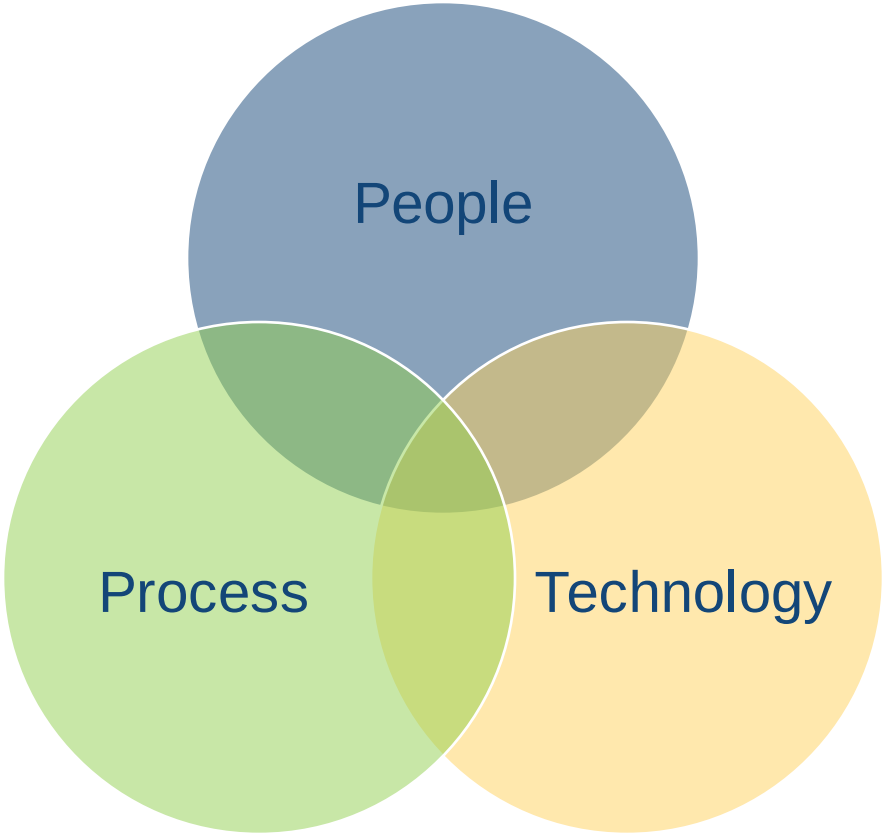
TMF Compliance in the TMF Lifecycle



Source: A Fisher, MHRA (HSRAA Conference, May 2019) (amended graphic with The Gap defined)

Case Study: 60 Days to Transfer 25 Studies

- Scope: We had 60 days to help a customer transfer 25 studies in various stages of lifecycle, from multiple source
  - Stats: 25 studies, 80k documents, most sitting in Veeva, some migrated into Veeva from other source systems, mix of open and closed studies, etc.
  - Kivo provided the software and ran the project. We defined the process. We worked directly with the sponsor partner managing the Veeva system transfer.
  - We had to get rigorous around aligning people, process, and technology to make it happen – good project management is essential
- We are going to use this project to frame the best practices that we've developed at Kivo and show how they enabled us to manage the complexities and challenges of moving content that has so many variances.


People
Process
Technology

People

Key Considerations

- Identified stakeholders very early and got explicit alignment on ownership and deadlines
- Every party (vendor(s), CRO, sponsor) needs clear roles and ownership
- Kivo was on point. Full stop. Someone has to be in charge and drive the process.
- Create regular touch points and check-ins – You need time allocated *before* issues arise

Process

Key Considerations

- Well defined process to ensure data integrity
- A written migration plan with quality steps embedded
- Testing steps to ensure the variables in the data being transferred have been considered
- Back out plan defined

What is Your Process?

- Define how the data will be transferred including:
  - Method of transfer
  - Content: Native & PDF
  - Meta Data included
  - Audit Trail format
- Define where the documents will be moved, what system are they moving into
- Define verification and quality steps including support for query management
- Define SLA for issue resolution

Approach and Consensus

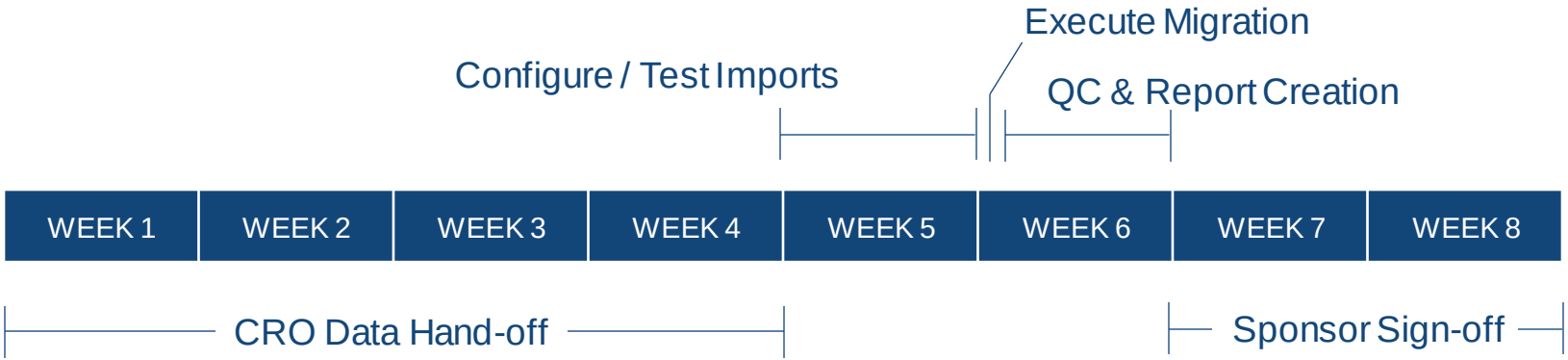
- Contract should have expectations for TMF, including TMF Transfer
- Your TMF Plan has defined QC process for transfer
  - Closeout activities documented and supported
- Your Functional teams should have clear responsibilities outlined
- Timeline expectations – How long do you have to review the content transferred

Technology

Our Approach

- TMF hand-off is the biggest point of compliance risk and also the “fumbliest”
  - Developed “touchless” migrations so that data is never out of a controlled system.
  - This shrinks migration plans and process checks by about 50%
- We build a validated, highly adaptive migration engine.
  - This allows us to use the same process and tools to handle all studies, despite variation in data structure, metadata, etc.
  - All 25 studies (~80 zips), once configured, could be migrated in about 2 hours.
- We fully integrated the audit trails from the source systems
  - This enables us to use tools to compare entries from the source exports and our db speeding up QC
- We conduct automated data integrity checks to verify that files are not corrupted or changed during import

Transfer Execution



Lessons Learned

CRO Collaboration – Key Consideration

- Think of your CRO as your partner and not just a vendor. Together you need to manage the health of your trial.
- Consider the last step at the beginning of the trial and not at the end.
- Waiting until the study has been closed makes for a challenging situation. Moving the content of the TMF is a critical step.
- Many CROs are not used to output format mattering and do not have stringent controls around the process
  - Study A rarely matches Study B

Inspection Readiness After the Transfer

- Inspection! A key step may still be on the horizon for your NDA, ensure the system you transfer your eTMF into can support inspections.
- Give Inspectors Controlled Access to the eTMF
- Understand the migration steps taken – these should be documented in a plan or SOP.
- Inspectors will need to know
  - where documents are in other Systems of Record
  - Access to full audit trail
  - How the files were controlled

Looking to the Future

- Walled gardens between vendors don't reflect how the industry works
- Exchange standards don't go far enough
- There are better tools on the near-term horizon to further optimize this
  - Direct API integrations between vendor platforms for programmatic transfer
  - Data transfer between tenants using two-party authorization
  - AI for document coding and mapping, metadata and placement QC


Thank You!