Practical Image Management for Pharma

Experiences and Directions. Use of Open Source

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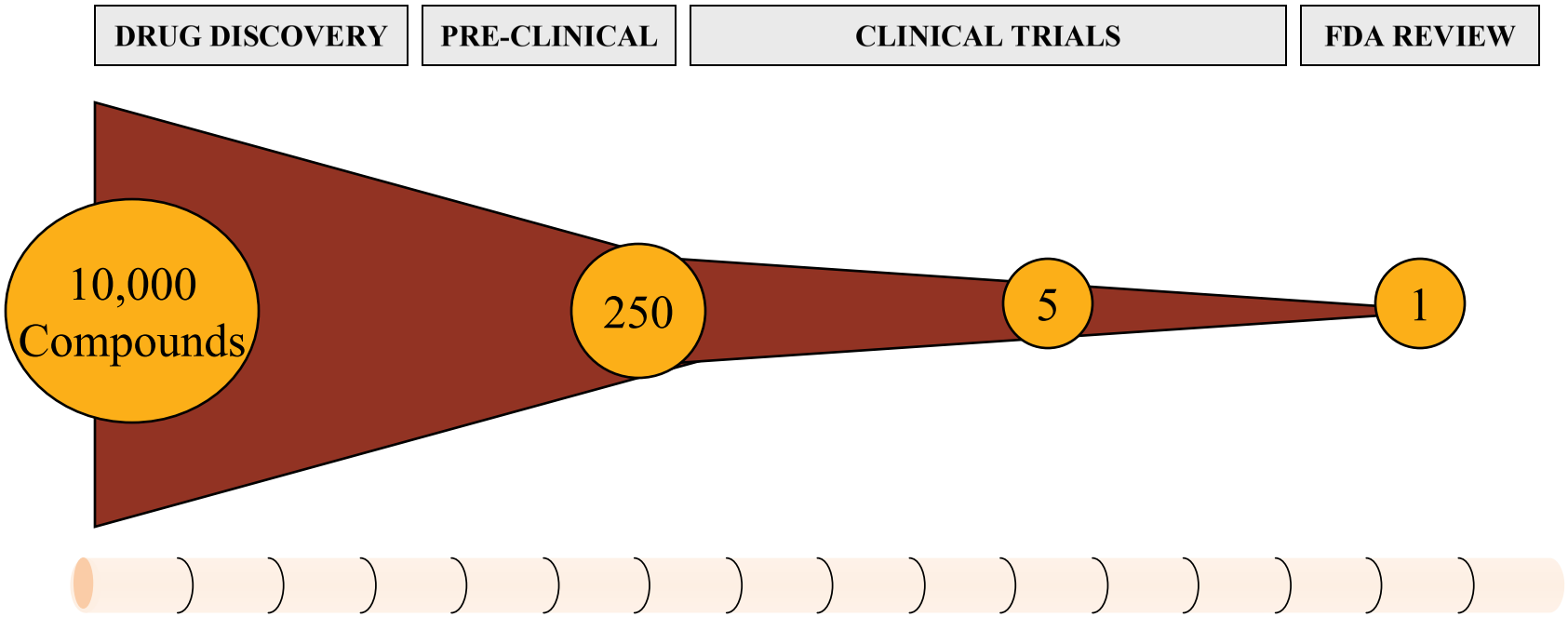
Agenda

- Introduction
- Drug Development, Imaging Trial Overview
- Why Pharma Image Management
- Objectives and Novartis Status
- Public Domain, Opportunities & Challenges

Drug Development Overview



- Imaging as a Leading Indicator
- Goal: Shorten Critical Path, time to market

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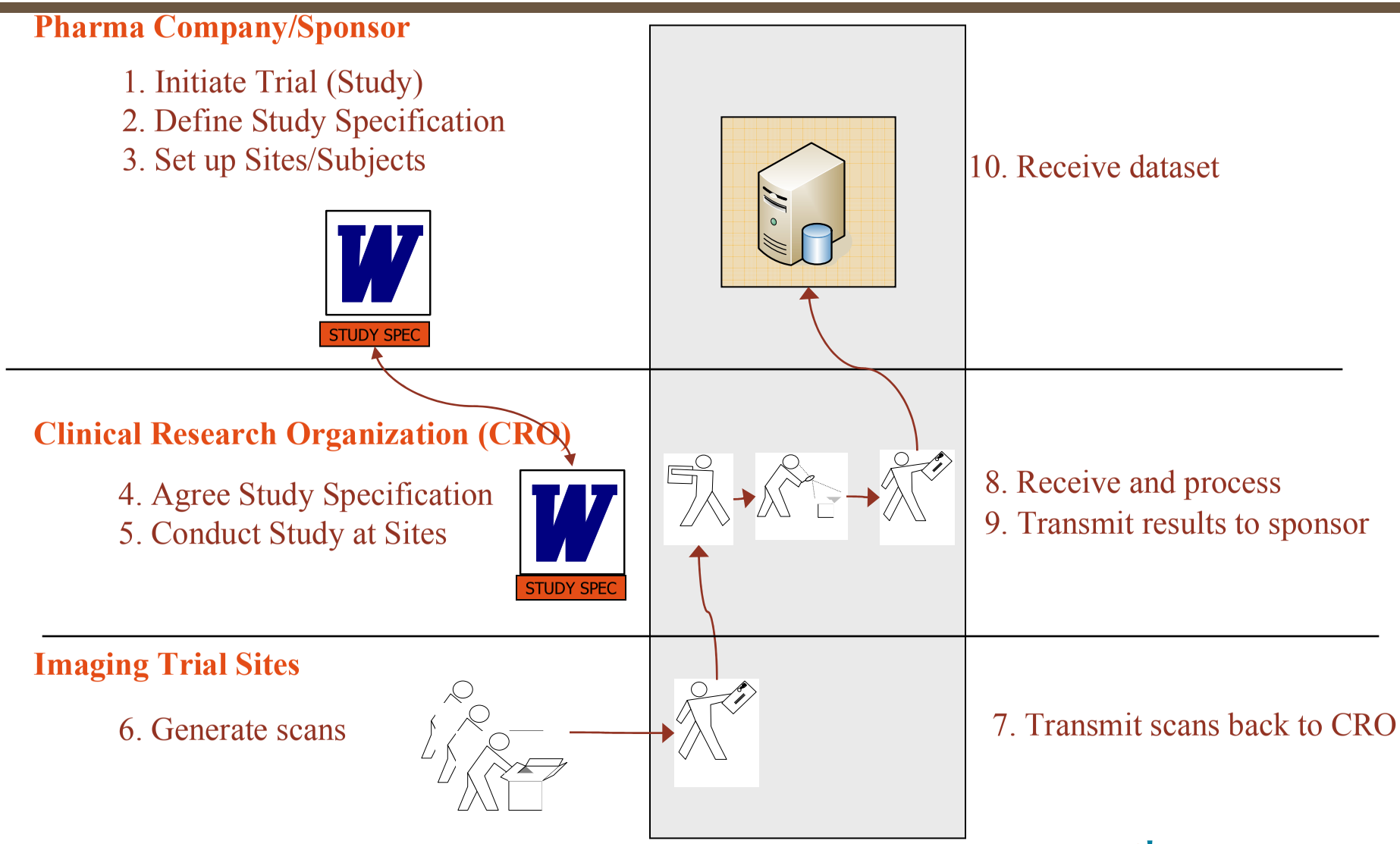
Imaging Trial Overview



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Environment Challenges

Why Pharma Image Management

- Data Access/Control
  - *Access*: Data scattered, proprietary formats, inconsistent metadata structure; therefore request-based access, not timely, expensive
  - Limited sponsor control over images or data management process
- Data Flow
  - *Transfers:* ftp or media/courier based, process disjointed, not audit trailed, lack of anonymization tools, no opportunity to improve process
  - *Little opportunity to customize process*: What about specialized sub-evaluations, secondary analysis by CRO, by Novartis?
- Data Quality
  - highly variable, no way for sponsor to judge or impact quality

Objective: Own the Data

1/3

Establish ownership of the data using central repository

- immediate, cost-effective access to the image data
  - Image data/metadata review and **post-processing**
  - Data submission, sharing, and collaboration at a global level
  - Improved decision support for clinicians, scientists, management
- consistent data quality standards (structural)

Objective: Flexible Workflow

2/3

Enable enhanced CRO Management capability

- Provide flexibility in CRO contracts
- Increase transparency/accountability of CRO
  - Ongoing data and process quality monitoring
  - Reduce turnaround time for issue resolution
- Disaggregate functions between CROs

Objective: Reach out to the Sites

3/3

Get the sites to

- format the data right (anonymization, data structure)
- acquire images consistently across sites
- without spending too much effort
- (on-site error correction, quality feedback, analysis, …)

Tools Currently Used

1. Central image hub, core platform for quality checking, image exchange, monitoring
2. Open source tool for de-identification and image shipment – deployment at core labs, sites
3. Internal post-processing using fully automatic algorithms

Work in Progress

- more algorithms
  - establish standard interfaces beyond DICOM to plug-and-play external algorithms
  - fully automatized algorithms for analysis, feature extraction, quality control
- impact site image quality
  - harmonize acquisitions at site (e.g. contrast)
  - shorten feedback loop (e.g. unacceptable motion)

Used Semantics and Interfaces

- DICOM (file) for images, results, XML message for metadata, data model
- XML for CRO image quality *contracts*
  - Example: accept image if resolution within certain range
  - DICOM tag based
  - Also used for formalizing algorithm input requirements
- DICOM (message) for transport, when needed

Pharma and Public Domain

1: Open Interfaces, Data Models

- Novartis has future interface needs
  - service definitions, APIs for image transport
  - a more comprehensive language to describe DICOM conformance/ the DICOM standard
  - plug-and-play algorithms
- In Pharma, major quest for consolidating heterogeneous systems using data standardization and interfaces
- similar to the example of DICOM, Pharma starting to embrace community-driven standards. Increasing efforts to contribute back (HL7, CDISC, DICOM, IHE)

Pharma and Public Domain

2: Open Source Software, Advantages

- Currently a wealth of open source software a length ahead of commercial products
- Collaborative approach for user requirement gathering, reference applications in pre-competitive areas
- Open source tools more easily adopted by partners
- Tools will speed up adoption of standards
- Open question with regards to OSS role in HA acceptance of automatic algorithms used for submission

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Open Source: Challenges

- Looking for the quick start manual
- Maintenance, customizations, hosting, SLA
- FDA 21 CFR Part 11
- avoid in-house coding for systems used in regulated endpoints
- need contracted service provider for full lifecycle management
- need to establish translation path from discovery usage to regulated type

Thank you!

- Questions, comments, other topics?

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