PAPERLESS CLINICAL TRIALS: HOW AND WHY

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AGENDA

- Why paperless?
  - Benefits and Importance
- How to move toward a paperless clinical trial
  - Practical tips

WHY PAPERLESS

Paper	Electronic
No centralized location for document	One seamless portal, easy communication and sharing of documentation
Multiple log ins	One log in, one system to train on
Slow work flow, frequent duplication	Share documents across stages and indications Notifications

BARRIERS TO A PAPERLESS ENVIRONMENT

Low comfort level with technology

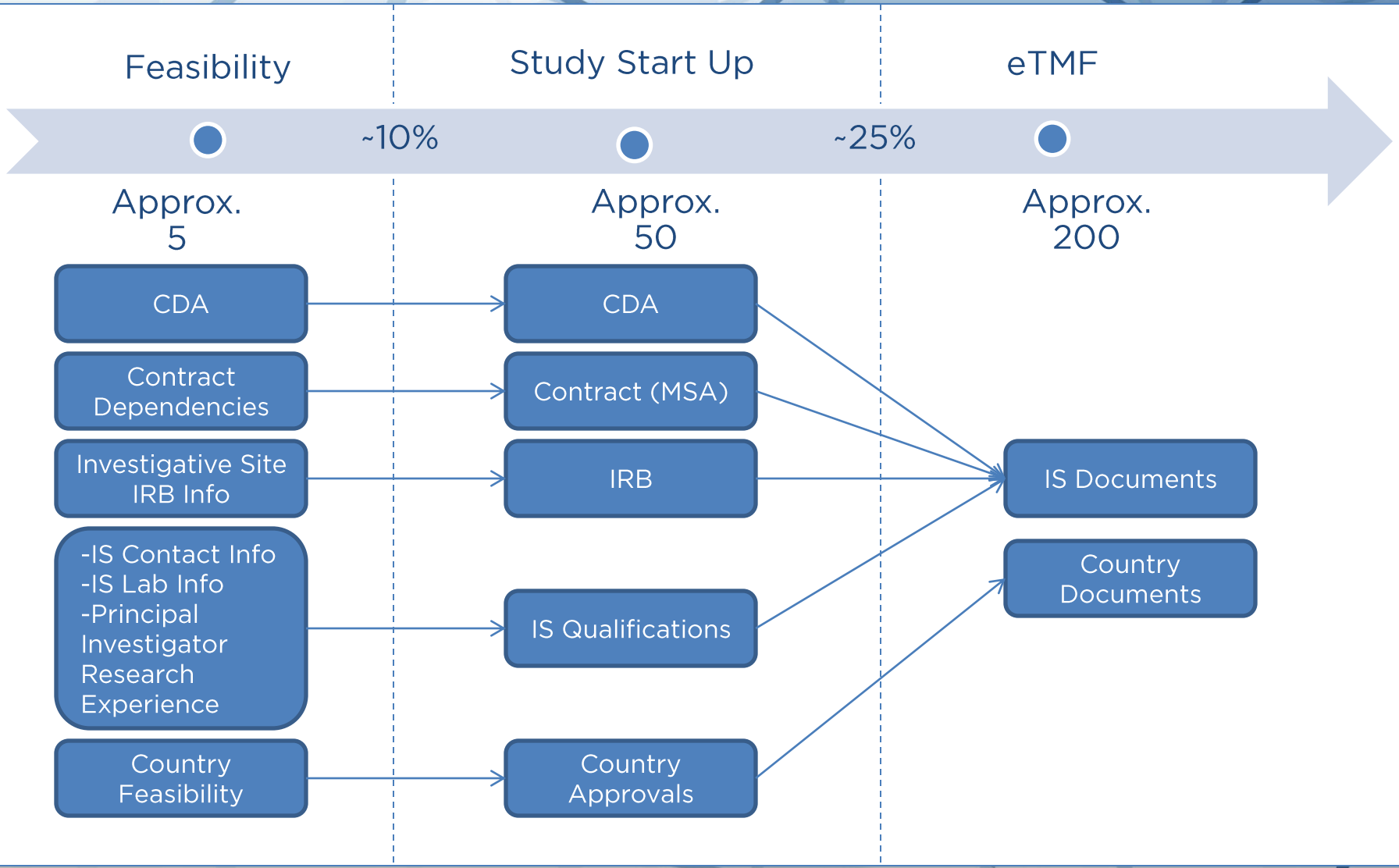
Regulatory Confusion Digital Signatures vs. Electronic Signatures

Multi-vendor Structure

Cost

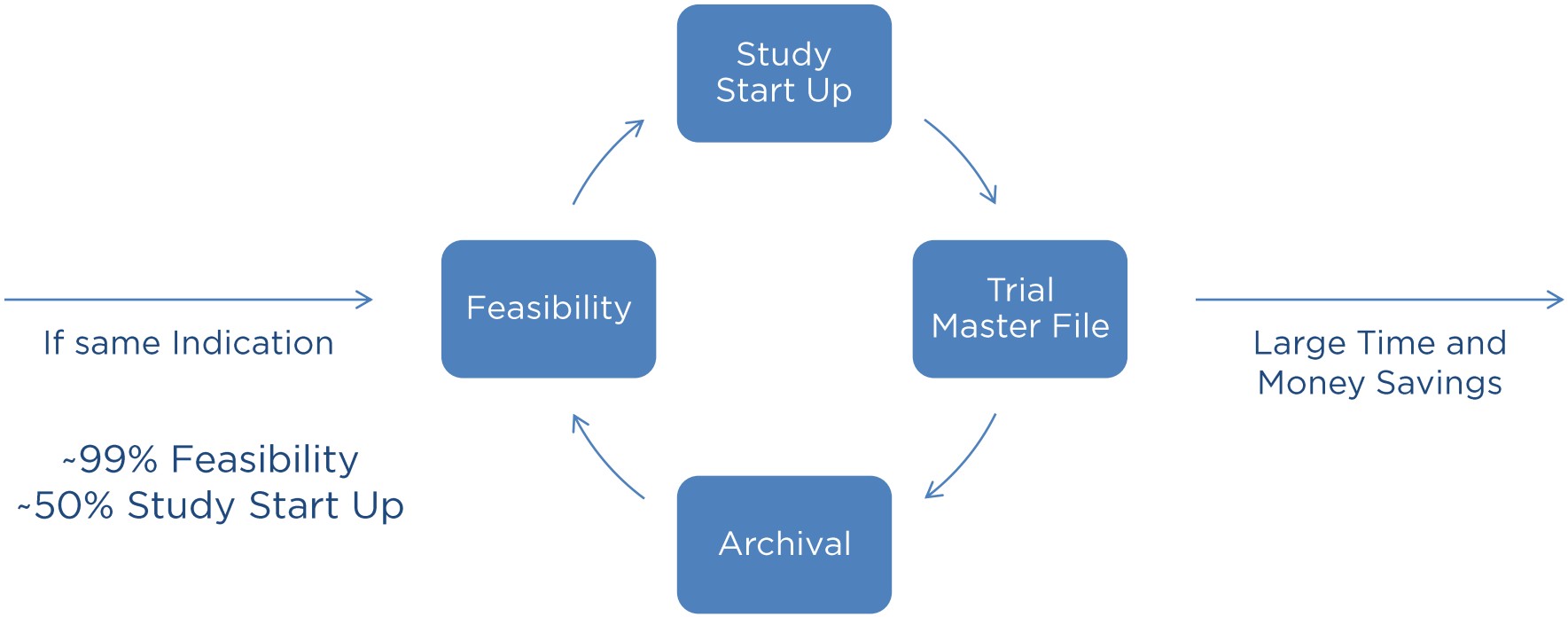
SMART DIGITIZATION

SELECT AN INTEGRATED PLATFORM THAT CONNECTS FEASIBILITY, STUDY START UP & ETMF



TRANSPERFECT LIFE SCIENCES

ENSURE THAT THE PLATFORM CAN SHARE DATA ACROSS PROCESS STEPS



BUILD A ROBUST DATABASE

IRB Listing
- Location
- Meeting Schedule
- Required Documents

Investigative Site Listing
- Contact Information
- Qualification Documents
- IRB Information
- Lab Information
- Indication/Therapeutic Area
- EDC/Subject Enrollment Data

Country Regulatory Listing
- Required Documents
- Submission Requirements

Patient Recruitment Listing
- Screening Information
- Investigative Site Information
- Study Information

DIGITAL MONITORING REPORTS

Provide an efficient mechanism to collect clinical information digitally.

Instead of filling out monitoring visit reports on paper forms, CRAs should be able to fill them out digitally based on a template available in eClinical system.

DIGITAL MONITORING REPORTS

Benefits:

- Large savings in reviewer productivity
- Helps eliminate multiple cluttered Excel trackers
- Bypass paper inventory hassles
- Avoid scanning, OCR, initial base coding

All of which require enormous amounts of manual labor, hence, of course, increased costs decreased efficiency.

PRACTICAL SITE TIPS

- Site
  - Keep updated e-versions of all frequently requested documents
  - Be proactive: Suggest e-submissions when working with CROs and Sponsors
  - Continuing education for site staff

PRACTICAL CRO Sponsor Tips

- Get started early: e-feasbility and study start up
- Be ahead of the curve: Regulatory moving toward electronic access
- Continuing education for staff

BENEFITS

Over time it eliminates the need to buy listings from 3rd party vendors for each new study

It offers a set of good pre-qualified investigative sites with their proven track records from past studies

It provides reliable and readily available information about essential study parties

- IRBs
- Sites
- Countries

QUESTIONS?

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