



# LEVERAGING CLINICAL DATA TO STREAMLINE GLOBAL DEVELOPMENT

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# AGENDA

- What has been your biggest cost “guzzler”?
- Smart Digitization
- Effective Study Archiving Process
- Robust Analytics

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BIGGEST COST “GUZZLERS”?



PAPER



# FORCES MANY DUPLICATE COPIES OF THE SAME DOCUMENT IN MULTIPLE LOCATIONS

There is no centralized location where all parties can instantly access documents on demand.



# PAPER REQUIRES MUCH MORE MANUAL LABOR TO MANAGE



The background of the slide is an abstract, layered geometric pattern. It consists of overlapping, semi-transparent shapes in various shades of blue, from light sky blue to deep navy blue. The shapes are primarily circular and polygonal, creating a complex, crystalline or cellular structure. The overall effect is a sense of depth and movement, with the patterns appearing to shift and change as the viewer's perspective changes.

# SMART DIGITIZATION

# USE A ROBUST DIGITAL FORM CREATOR

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.

A robust digital form creator allows creating any type of forms that can be hosted directly in your platform.



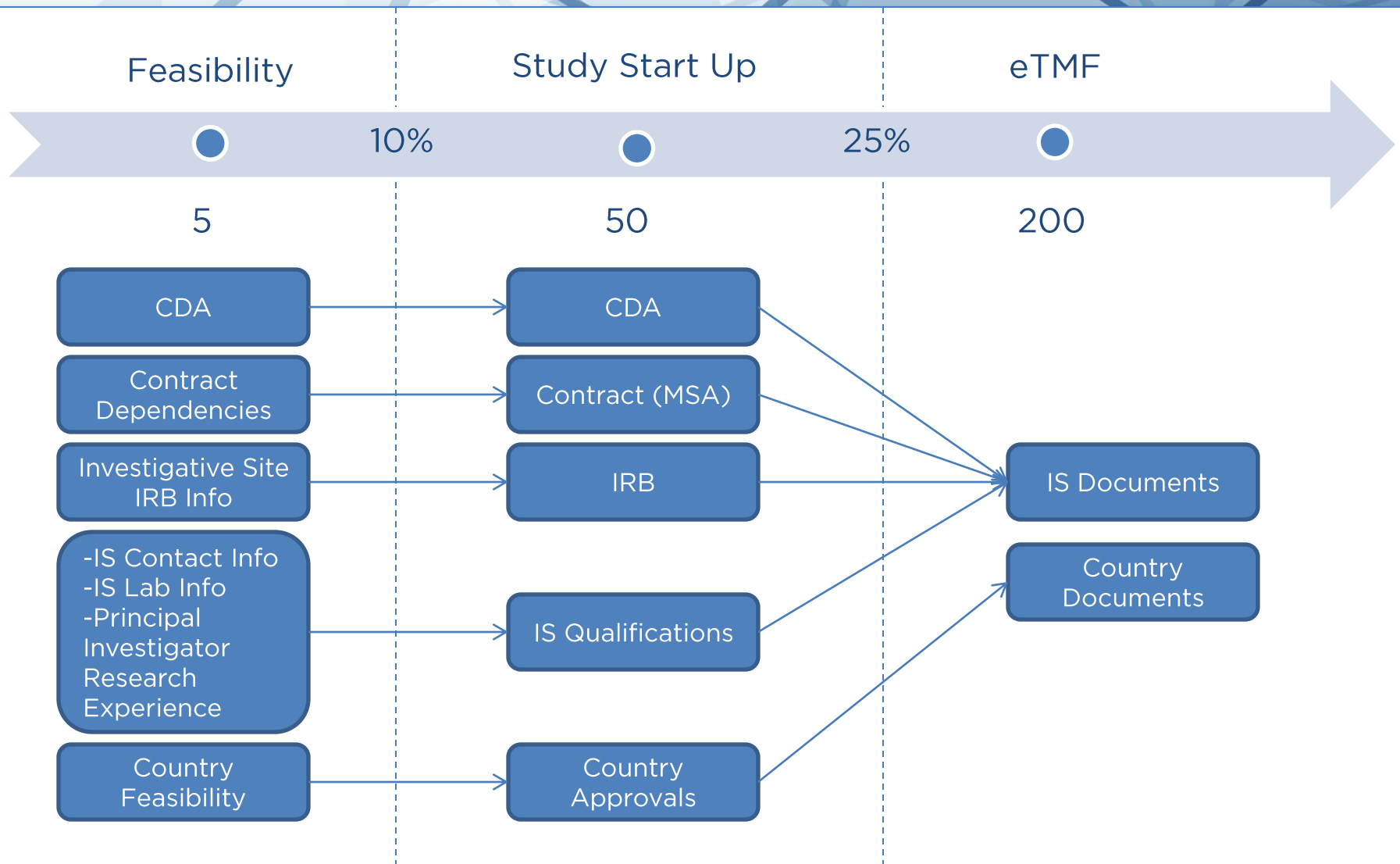
# USE A ROBUST DIGITAL FORM CREATOR

## Benefits

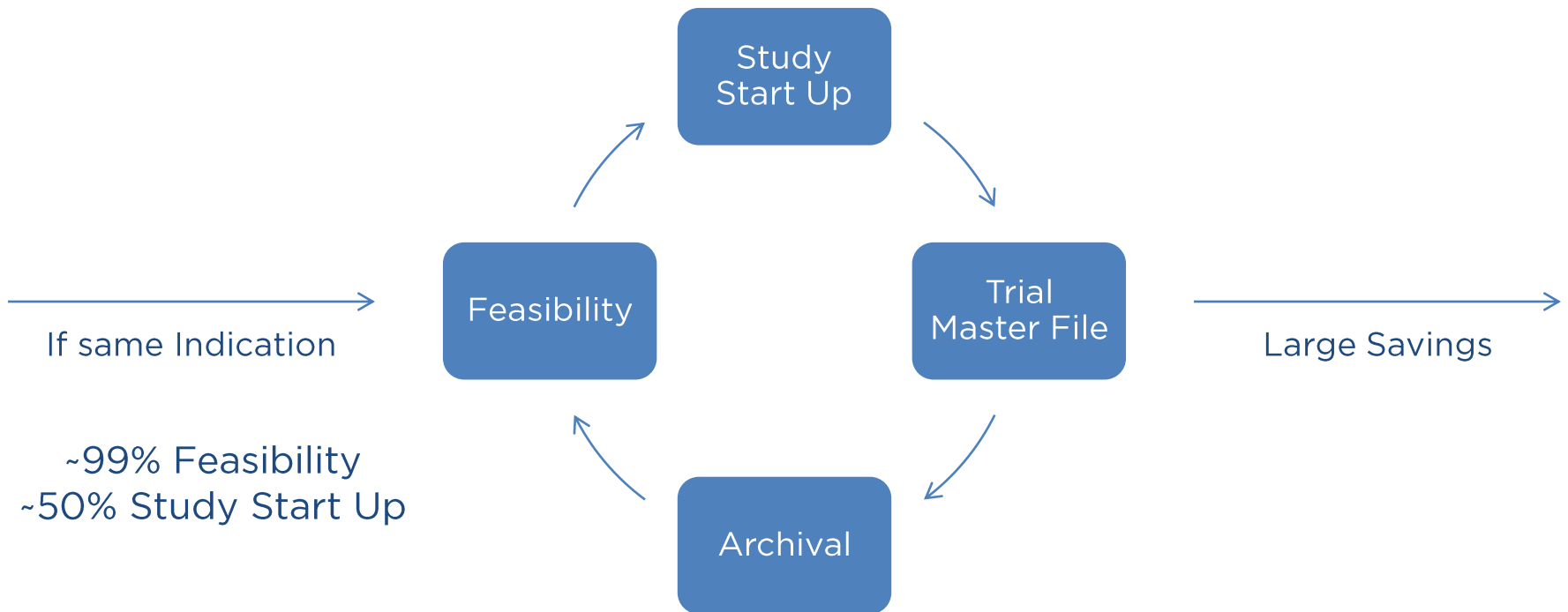
- Large savings in reviewer productivity
- Helps eliminate multiple cluttered Excel trackers
- Bypass paper inventory hassles
- Avoid scanning, OCR, initial base coding


All of which require enormous amounts of manual labor, hence, of course, increased COSTS.

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



# ENSURE THAT THE PLATFORM CAN SHARE DATA ACROSS PROCESS STEPS



The background features a complex, abstract pattern of overlapping, semi-transparent shapes in various shades of blue and white. The shapes resemble a network or a cellular structure, with some areas appearing more solid and others more ethereal. The overall effect is a textured, layered look that is both modern and organic.

# EFFECTIVE STUDY ARCHIVING PROCESS

# ARCHIVE DATA IN ENTITY LISTINGS - EXAMPLE

## 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

# BENEFITS

Over time it eliminates the need to get listings from 3<sup>rd</sup> 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

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# ROBUST ANALYTICS PLATFORM

# WHAT SHOULD YOU BE LOOKING FOR IN A GOOD ANALYTICS ENGINE?

Fully integrated with systems that you use to run your clinical studies.

Ability to easily exchange data with external systems over standard channels such as web services.

Ability to run strategic aggregate reports across all past and current studies to identify time lapses between phases, activities, and processes to help with future budget and schedule planning.

Ability to quickly extract initial sets of information about essential parties for each new study based on study characteristics such as indication or therapeutic area or location.



# SUMMARY

Smart  
Digitization

Effective  
Study  
Archiving  
Process

Robust  
Analytics  
Platform



The background of the slide is an abstract, layered geometric pattern. It consists of overlapping, semi-transparent shapes in various shades of blue and white, creating a complex, crystalline or cellular appearance. The shapes are irregular and interconnected, forming a network-like structure. A dark blue horizontal band is positioned in the center of the slide, containing the text.

QUESTIONS?

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