

Presentation for



Data Challenges in Adaptive Trials

PhUSE Annual Conference 2014

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Program Agenda

- 1 In scope / out of scope
- 2 Introduction to Adaptive Trials
- 3 Data challenges
- 4 Data architecture and data flows
- 5 Conclusions

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In scope / out of scope

IN

OUT

Adaptive Trials

Flexible Trials

Data Management

Statistical Methodology

IT landscape

Simulations

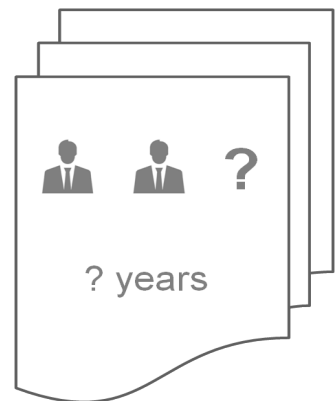
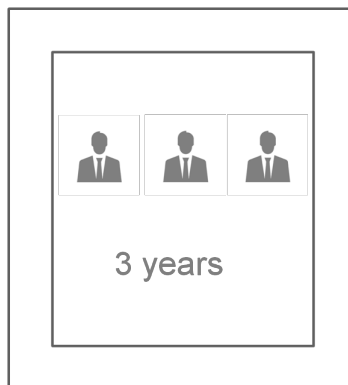
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Introduction to Adaptive Trials



Preplanned adaptations of one or more **trial elements** that are **modified** while the trial is underway based on an analysis of **interim data**

Introduction to Adaptive Trials

Adoption

- Across the industry, simple adaptive design trials (ADT) are used on approximately **one in five (20%)** trials. Most common:
 - Early study termination
 - Sample size re-estimation
 - Lower adoption for others (e.g. seamless phase II/III)
- Regulatory bodies (FDA, EMA) highly receptive of early phase adaptive trials (e.g. adaptive dose-finding studies in phase I/II)

Introduction to Adaptive Trials

Benefits



Better chances of finding optimal dose / population



Cost & time savings



Better understanding of treatment effect

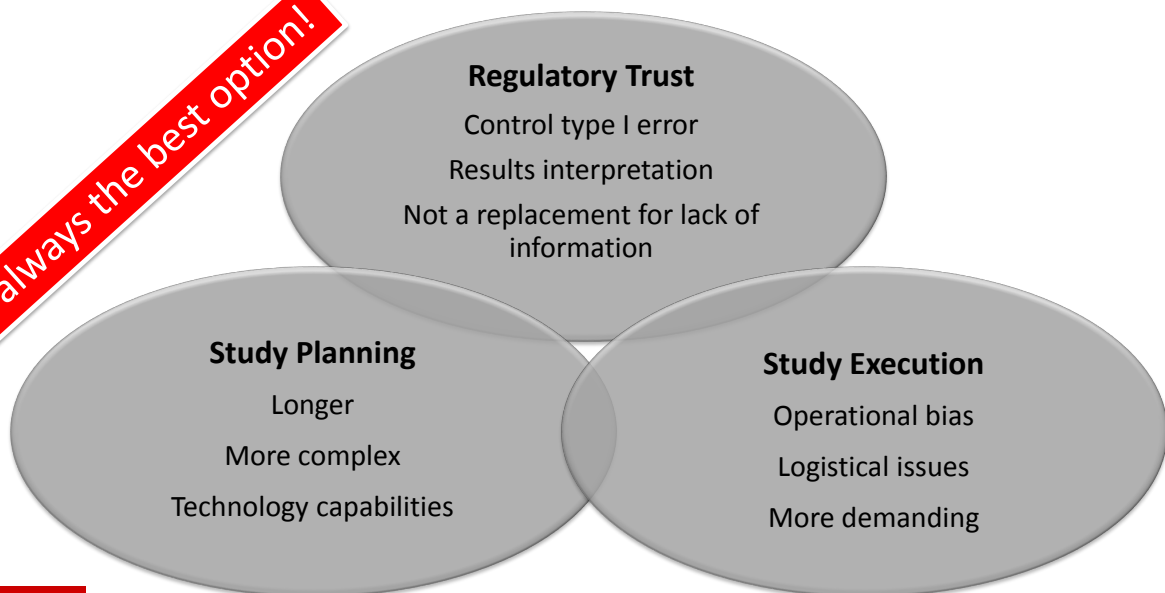


Reduce patient exposure

Introduction to Adaptive Trials

Risks

Not always the best option!

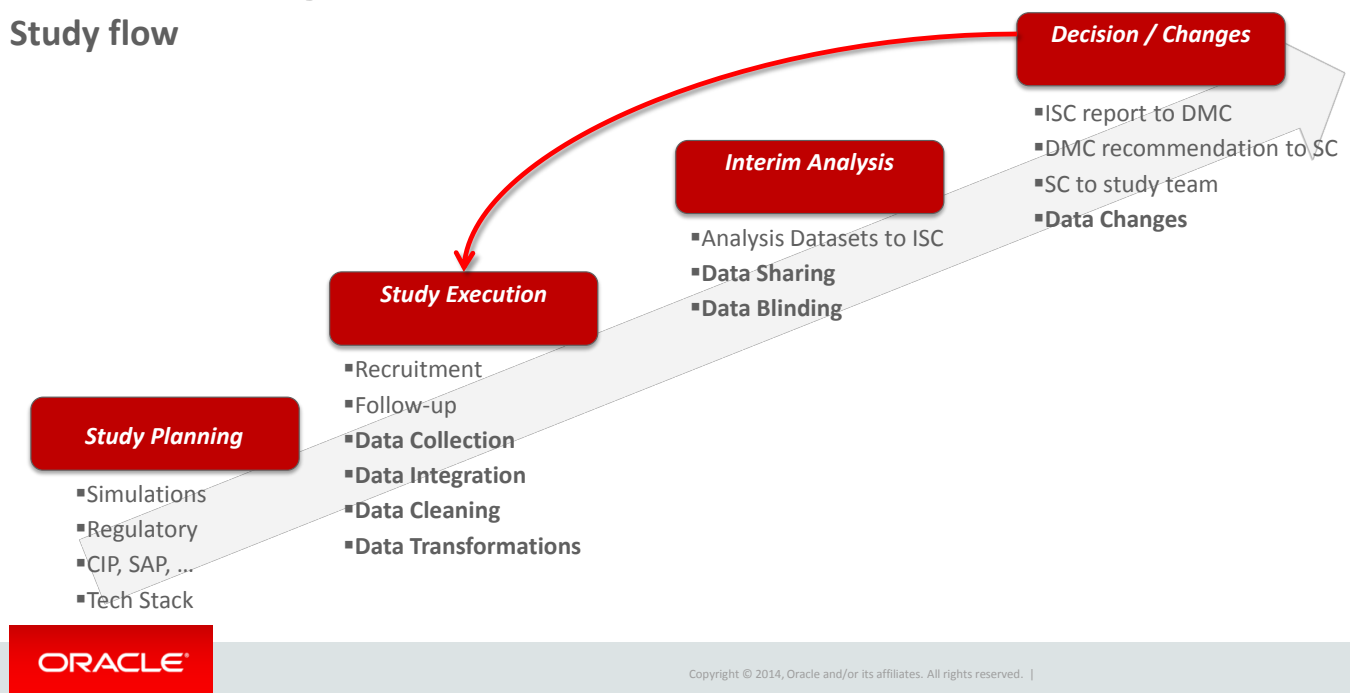


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Data challenges

Study flow



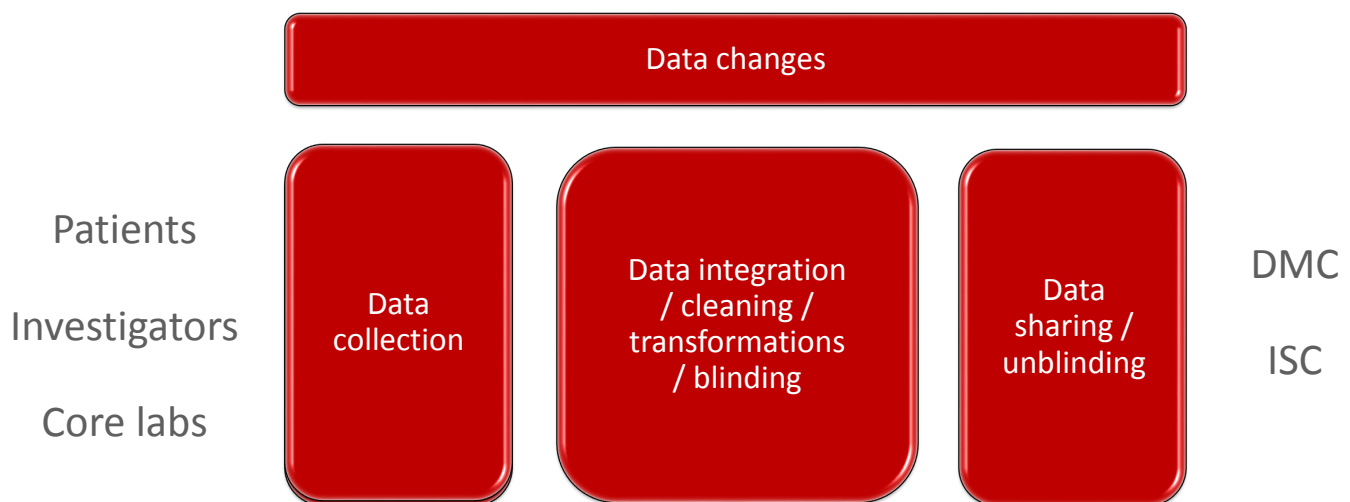
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Data architecture and data flows

An example

Study Team, Steering Committee



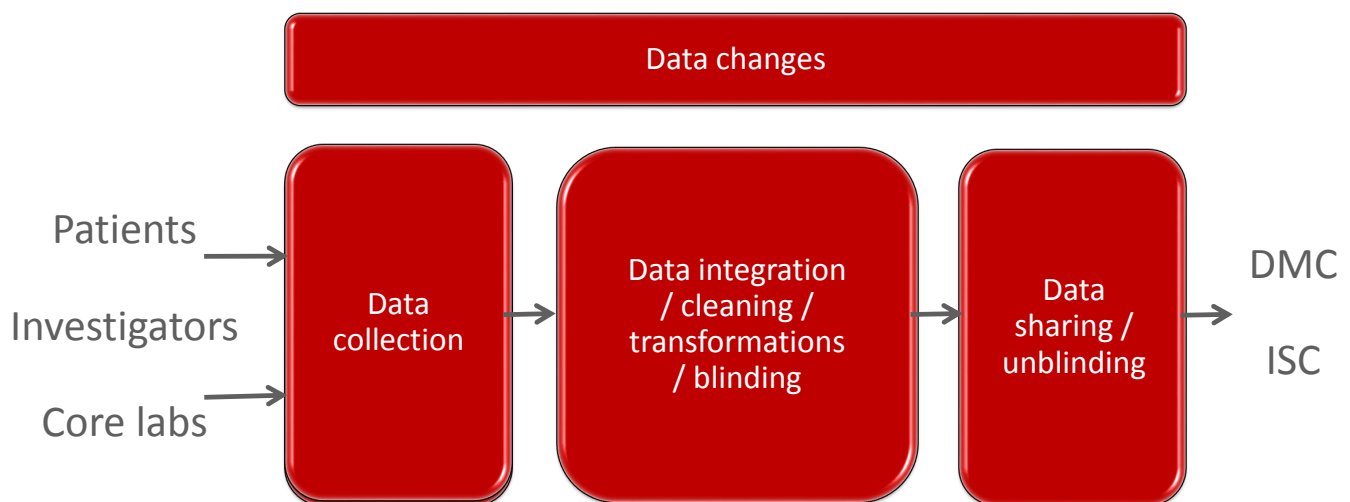
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Data architecture and data flows

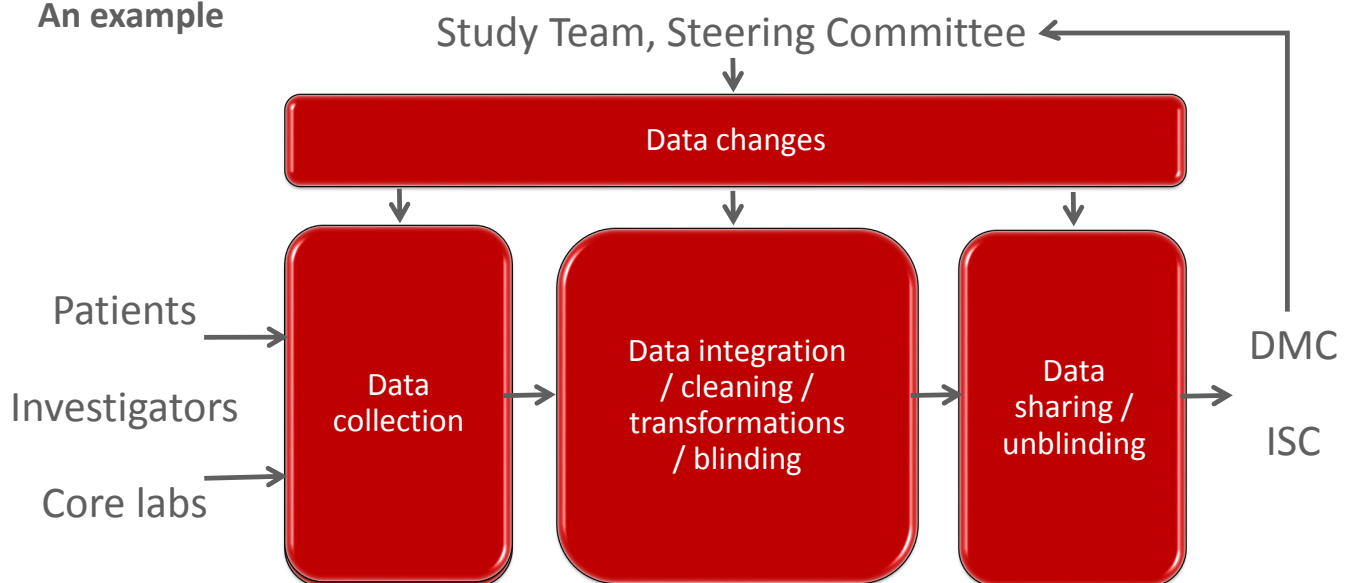
An example

Study Team, Steering Committee



Data architecture and data flows

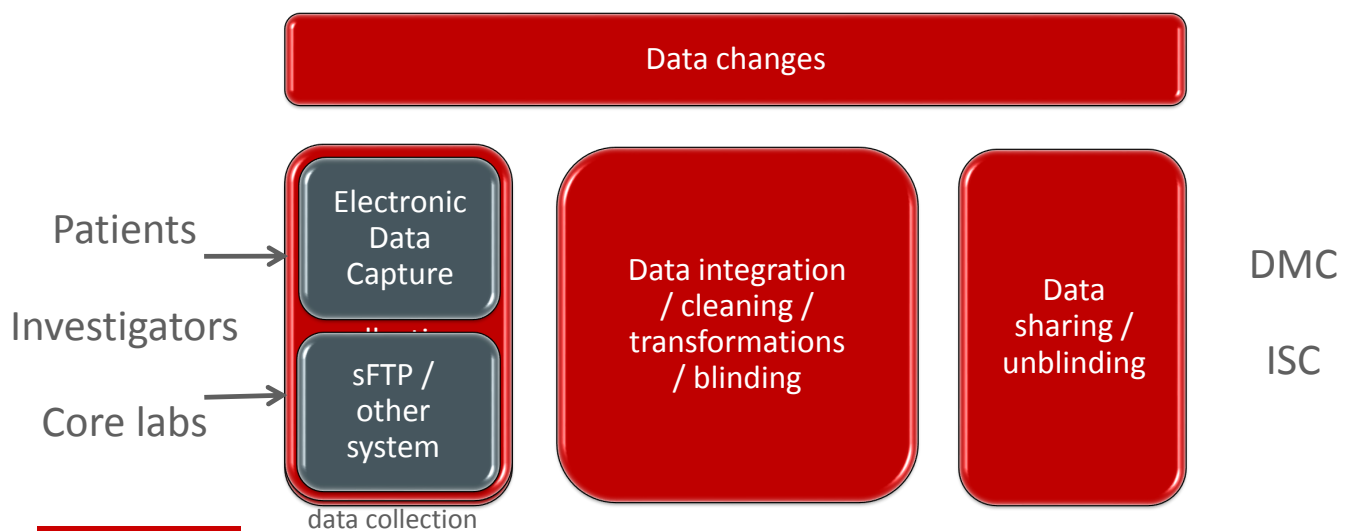
An example



Data architecture and data flows

An example

Study Team, Steering Committee



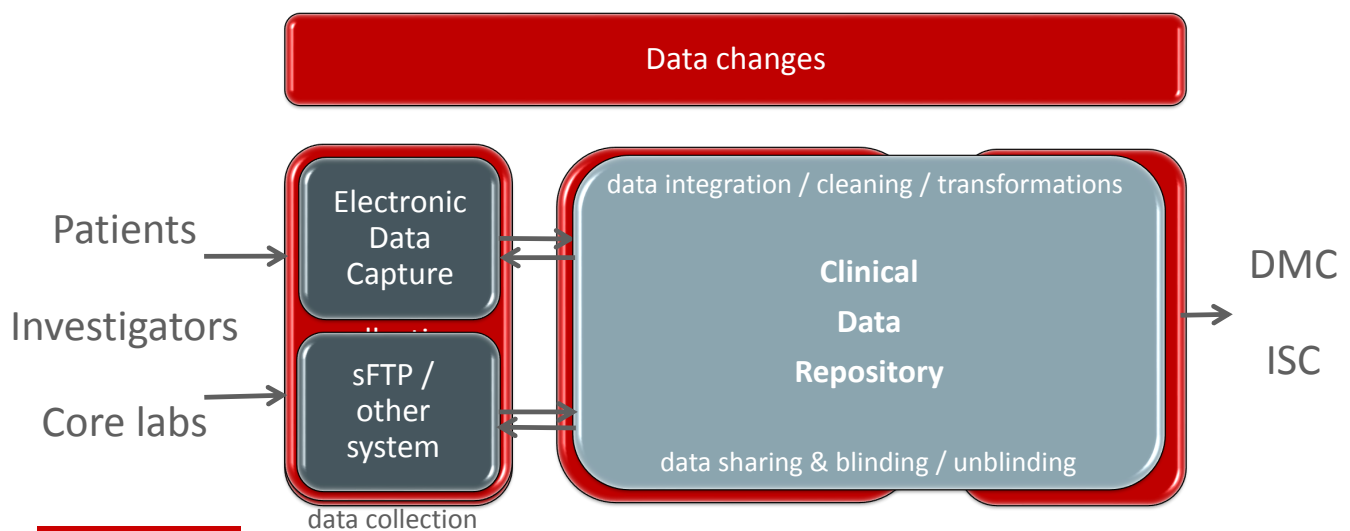
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Data architecture and data flows

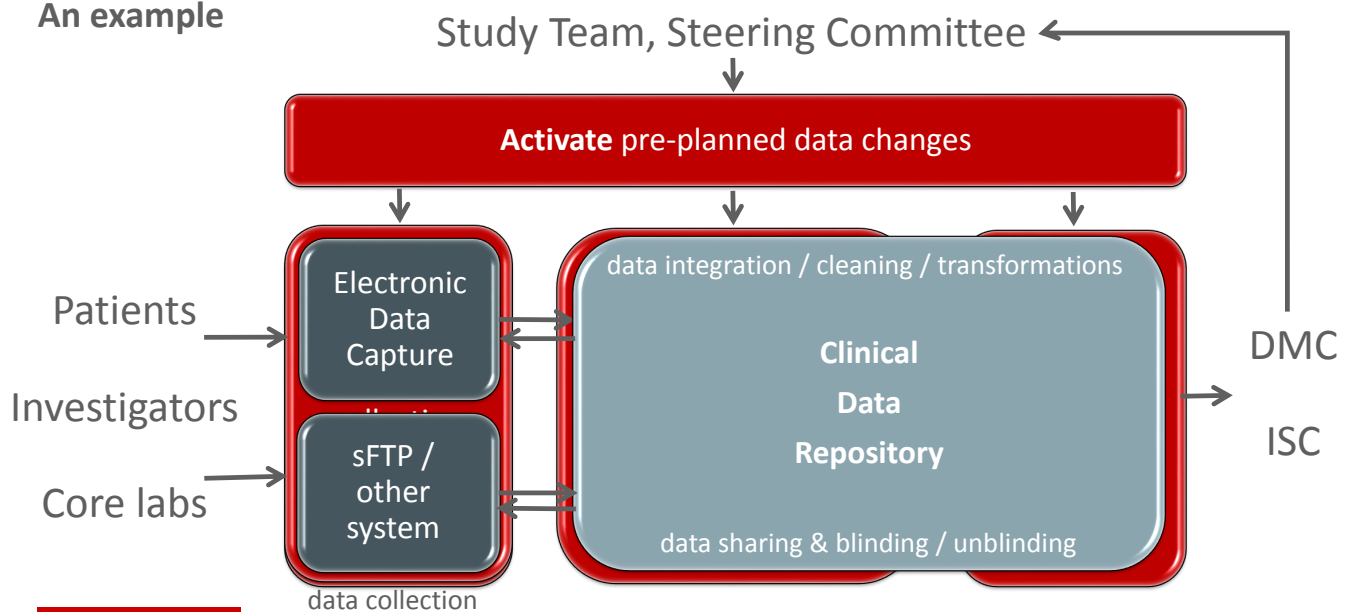
An example

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Data architecture and data flows

An example



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Conclusions

In short

- **One in five** trials is adaptive.
- Several benefits include substantial **cost** and **time savings**.
- **Risks** include data challenges, such as data collection, data integration / cleaning / transformation, and data sharing / blinding / changes.
- Electronic Data Capture (**EDC**) and Clinical Data Repository (**CDR**) systems **mitigate risks** associated with data handling in adaptive trials.

Conclusions

Moving forward

- Rise in use of **wireless technology** in clinical trials (e.g. sensors, wearable devices).
- Wireless technology can be used for **automatic data capture**.
- Benefits include reduction in the number of errors associated with manual entry, and **real-time** data capture (e.g. patient adherence, physiological parameters).

References

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