Assessing Efficacy of our Life Saving Drugs

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TransPerfect

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Agenda

- Background
- Why is drug assessment necessary
- How is endpoint adjudication managed today
- How can we make it more efficient

Background

- Focus of many pharmaceutical companies today is creating treatments for chronic conditions and diseases.
  - This shift results in:
    - Increase in development times and cost
    - Requirement of long term data to assess benefits and risks
    - Endpoint driven studies

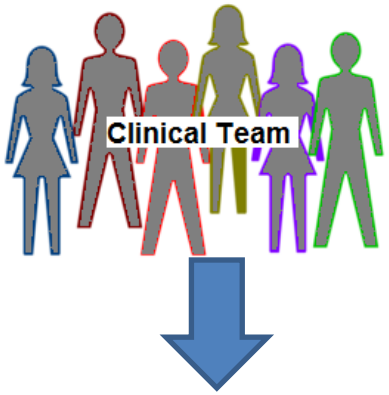
Why is drug assessment necessary?

- Allow regulatory authorities to monitor effect of the intervention on an ongoing basis
  - ensure drug or device safety
  - more sound and effective clinical trials

Who generally assesses these endpoints?

- Clinical Endpoint Committees (CEC)
  - Unbiased reviewers

How is endpoint adjudication managed today?



•Source Data Collection
•Send items to Clinical Project team
•Report endpoint

•Identify documents that need translation and submit to vendor
•Issue and resolve query for missing or incomplete items
•Compile endpoint package
•Submit to CEC

•Review package
•Issue and resolve query
•Complete adjudication

How can we make it more efficient?

Go Paperless

Drawbacks to Paper	Electronic Enhancements
No centralized location for packages	One seamless portal, easy communication and sharing of documentation
Documents need to be shipped to and from several parties including: site, CRO, Translations team, Adjudicators	Documents move from one party to the next in a single electronic platform
Slow work flow, frequent duplication	Decrease processing time and avoid duplicates with electronic identifiers
Adjudication results recorded on paper CRF need to be shipped to CRO and or Sponsor to identify patterns	Adjudication completed on same electronic platform and results are visible immediately

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SPONSOR

VISIBILITY INTO ALL CYCLE TIMES

CUSTOMIZED REPORTS

REAL TIME DATA ON KEY DELIVERABLES

CROS

FASTER PACKAGE ASSEMBLY

ONLINE QUERY

ONLINE CODING

ADJUDICATORS

REAL TIME ACCESS TO ENDPOINT

E-ADJUDICATION CARD BUILT IN

E-CRF CARD BUILT IN

10% DECREASE IN CEC ADJUDICATION TIME

30% DECREASE IN ENDPOINT AND PACKAGE PROCESSING TIME BY CRO

75% REDUCTION IN TRANSLATION TURNAROUND TIME

90% DECREASE IN SHIPPING COSTS

Additional benefits of Electronic Adjudication

- Allows Sponsor to design their own unique workflow
- Immediate reconciliation with EDC
- Easy access for international teams
- Data allows for power calculations, periodic safety reviews by Data Safety Monitoring Boards, sample-size re-estimation and other interim analyses, overall results for efficacy and safety analyses

Questions?

Thank You!