



Acceleration through Collaboration

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clinical | commercial | consulting | capital

Who I am.....

- 8 years experience
- Statistical Scientist
- Experienced Statistical Team Leader
 - Leading teams from 2-10 statisticians & programmers
 - Primary sponsor contact
- Lead UK resourcing team
- European representative on Global SOP Task Force

Background

- Why did I pick this topic?
- What is “Acceleration through Collaboration”?
- What is the aim of this presentation?

Overview

- Resourcing models
- Building effective relationships
- Recent initiatives at Quintiles

Resourcing Models

Sponsor specific pool of resource

– Benefits

- Increased consistency
- Reduction in potential delays in finding additional resource
- Changes in resourcing requirements can be agreed by prioritising deliverables within the program

– Challenges

- Keeping track of scope
- Inefficiencies caused by frequent re-prioritising
- Close communication between the sponsor and CRO is vital

Fee for service

– Benefits

- Sponsor can request work without having to agree scope up front
- CRO can spend less time managing scope

– Challenges

- Flexibility of CRO to changing priorities
- Ensuring close communication between the sponsor and CRO is vital

Whole study outsourcing

– Benefits

- Sponsor is free to progress with other work
- Sponsor has pre-selected the CRO so only needs to agree the budget and set the aims
- CRO has more responsibility and freedom to make decisions
- Longterm partnership

– Challenges

- Ensuring that all relevant information is available to the project team

Global worksharing

– Benefits

- Separate offices can be used for unblinded DSMB/ Interim analyses
- Low-cost countries available while retaining the experience of more established offices
- Larger pool of resource available
- 24 hour working

– Challenges

- Ensuring consistency across offices
- Communication

Effective Partnerships

Effective Partnerships

- Joint goals
 - Beneficial to establish high-level joint goals between the sponsor and the CRO
 - Usually based around efficiency or productivity gain

Effective Partnerships

- Detailed start-up meetings
 - If possible, meet face-to-face
 - Include an overview of the whole program, as well as the study itself
 - Address any potential issues
 - Ensure that processes for both companies are described in detail
 - Describe the purpose of each deliverable
 - Discuss expectations of both teams in regard to timelines and resource

Effective Partnerships

- Agree lines of communication
 - Small misunderstandings can have a big impact
 - Some sponsors prefer a single method of communication
 - No right or wrong answer!
 - Whichever method is used it is essential that the decisions are clearly documented
 - Quintiles Question and Response tracker is regularly used:

Effective Partnerships

Questions and Responses Tracker (Specs, Shells, CRF and SAP Issues)

(Most Recent at the top, in general red text = subject of question, black text=question details, blue text=response)

02. LAB – normal ranges for Bilirubin	
Carrie Eason (12SEP2006)	Could you please, confirm that the normal ranges you specified in your comments for Bilirubin (see email sent on 25/04/2006) are correct.
Joe Bloggs (12SEP2006)	We had doubts about the normal limits ourselves and rechecked them with the lab. They confirmed that these were the limits that should be used.

01. AE Questions – Table 14-10.4	
Carrie Eason (23Aug2006)	In the AE table 14-10.4 , the denominator calculations are not clear to me. In other AE tables each patient is only represented once in the table (so a patient having multiple serious AEs will only be counted once as per interim) but for this particular table (which was not present in the interim) the top line indicates a number of patients (always with a percentage of 100?), but the subsequent rows show numbers of events. If the percentage calculations for numbers of events are based on number of patients – the percentages could easily add up to over 100% where a few patients have multiple events. Could you clarify the way you would expect percentages to be calculated in these tables – or if percentages should be presented at all? Thanks
Jo Bloggs (25Aug2006)	On reflection it will be best to just quote the Ns for this table but also (if possible) to include an extra 2 lines in the table: to summarise the number of nausea events reported and the number of vomiting events reported. Let me know if this is straight-forward to do.

Effective Partnerships

– Be flexible

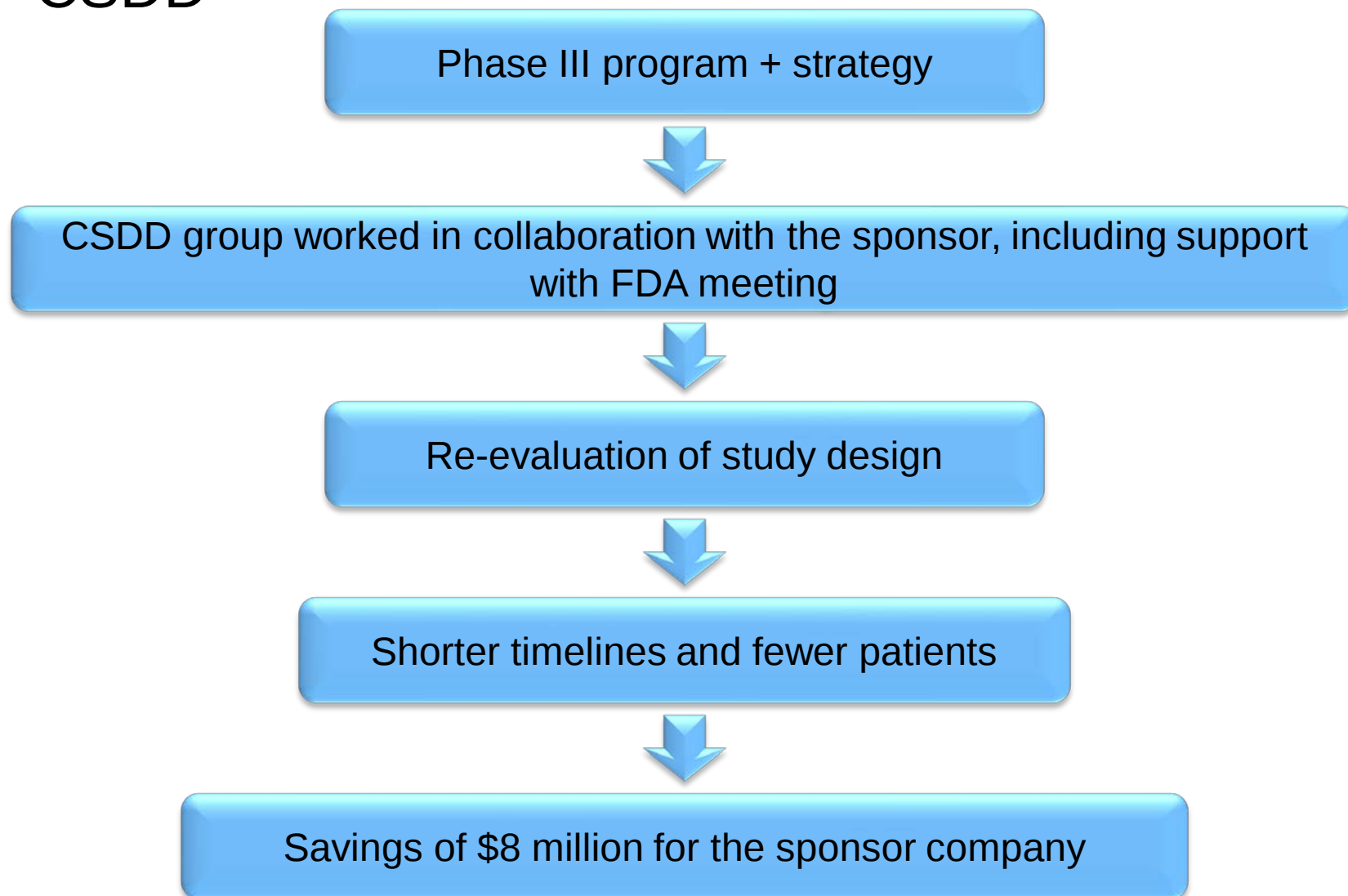
- Flexibility is required from both the CRO and the sponsor to build an effective partnership
- Important that sponsors understand that the CRO will have a large number of studies ongoing at any one time
- The sponsor must keep the CRO up to date with changes to a study to enable the CRO to be flexible
- Crucial that the CRO understand that sponsors can not anticipate all changes
- CRO must remember they are not the only ones under pressure

Recent initiatives at Quintiles

CSDD

- Center for **S**tatistics in **D**rug **D**evelopment
- Who are the CSDD?
- What are the aims of the group?
- How can the CSDD group help accelerate clinical development?

CSDD

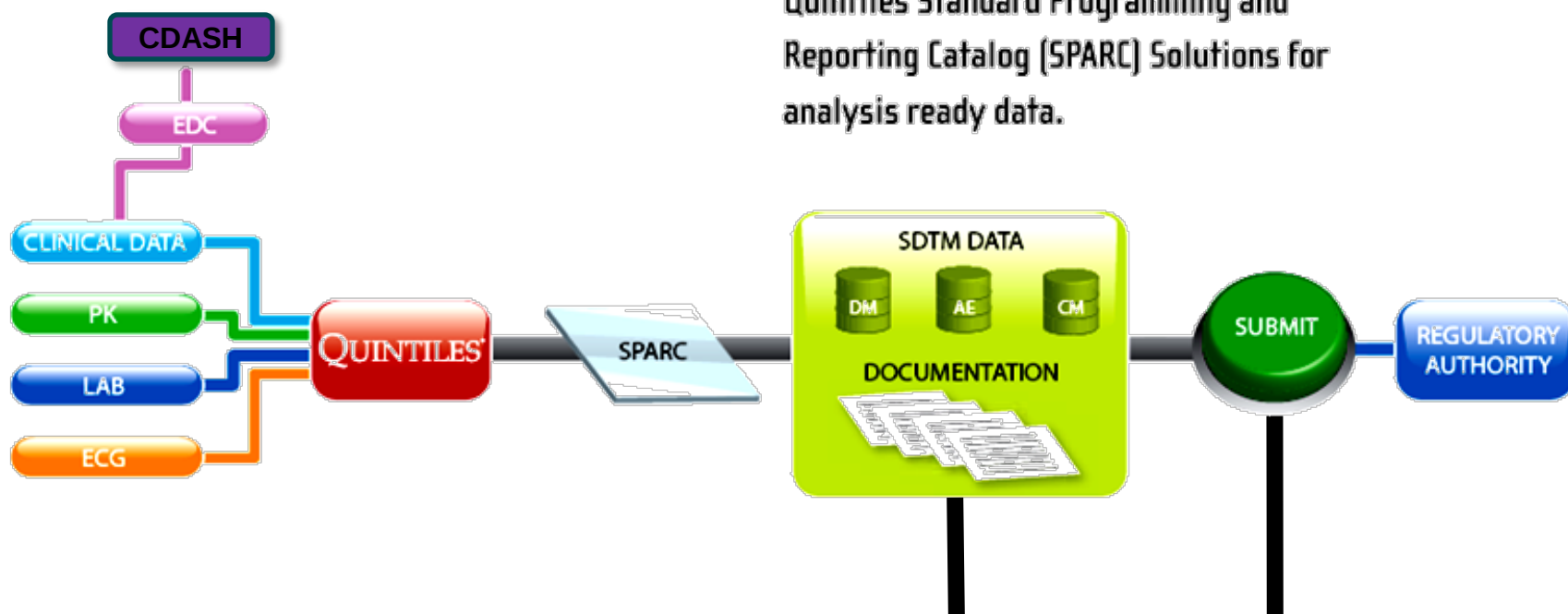


SPARC

- **Standard Programming and Reporting Catalog**
 - Major initiative running across data management and biostatistics
 - Tool used on an EDC platform to collect, clean, transfer and transform data using CDISC standards

SPARC

Quintiles Standard Programming and Reporting Catalog (SPARC) Solutions for analysis ready data.



SPARC

– What are the benefits of SPARC?

- SDTM dataset production
- ADaM dataset production
- Regulatory guideline compliance
- Quality
- Efficiency
- Cost effective

New for 2010 – Standard Delivery Model

– Objectives:

Target **cycle time of 3 business days** post database lock and unblinding of **Topline TLFs**

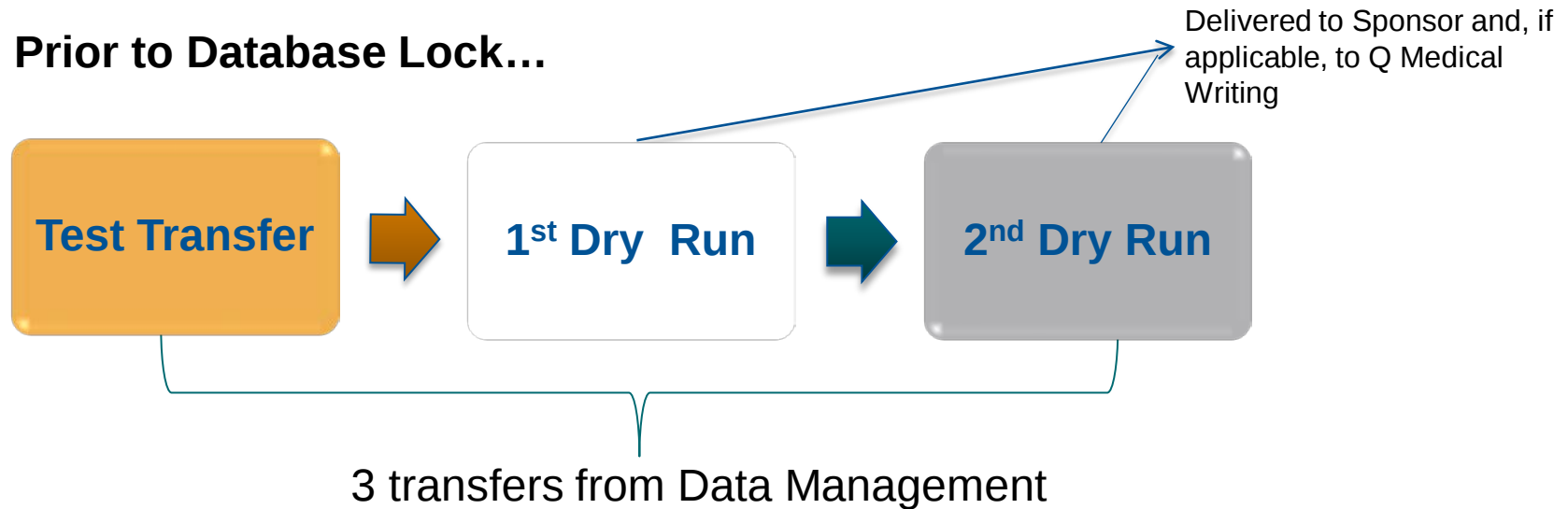
Target **cycle time of 10 business days** post database lock and unblinding of **final TLFs**

Reduce the post database lock deliveries from one draft and one final to **one final delivery**

Plan “dry runs” to occur prior to database lock and provide the rationale, in terms of **purpose and benefit**, for each delivery

New for 2010 - Standard Delivery Model QUINTILES®

Prior to Database Lock...



After Database Lock...



Conclusions

- There are many ways in which CRO's and sponsor companies can work together to ensure effectiveness and efficiency
- Important to consider new approaches
- As sponsors and CRO's work alongside each other more and more it is imperative that successful collaboration take place so that the joint goal of accelerating drug development can be achieved

Questions?

Do you see a change in the way that CROs and sponsor companies work together?

What do you think is the most important thing that a CRO could do to accelerate clinical development?