

Implementing Risk-Based Management (RBM) and Source Data Verification (SDV)

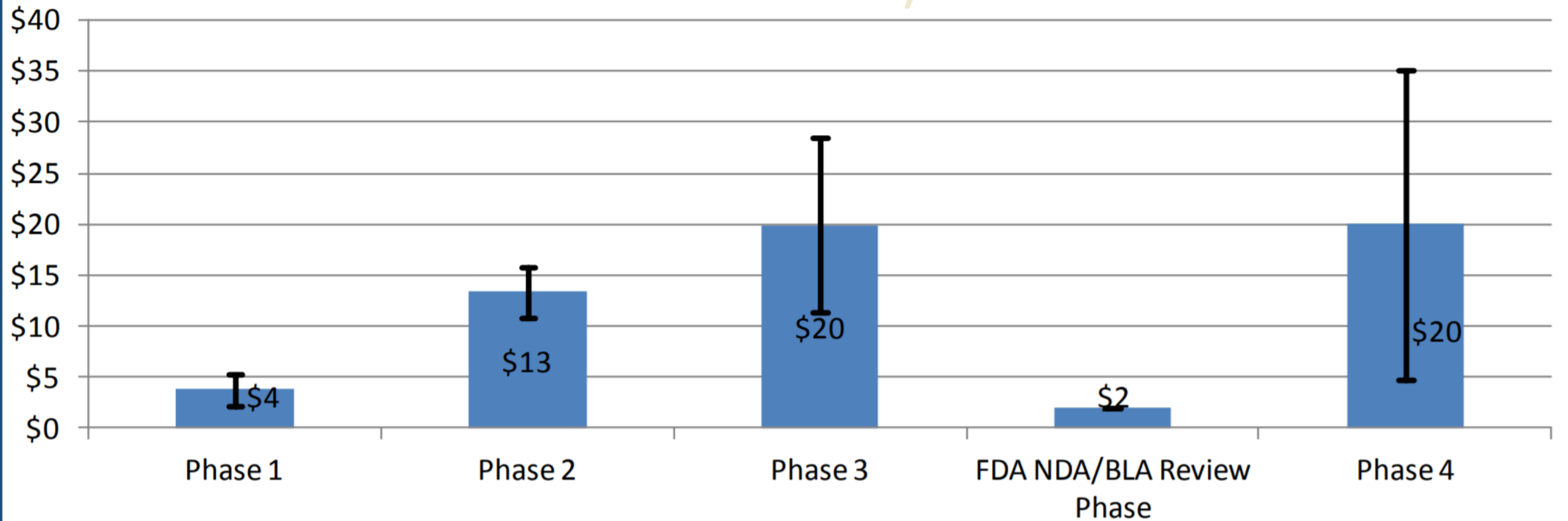
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What problem are we trying to solve?

If you are going to implement something, why?

Average Per-Study Costs by Phase (in \$ Millions)



Examination of clinical trial costs and barriers for drug development, U.S. Department of Health and Human Services, 2014

How much to SDV and Monitoring?

Activity	Phase I	Phase II	Phase III	Phase IV
SDV	\$326,437 15.32%	\$406,038 5.34%	\$400,173 3.52%	\$353,602 3.10%
Site Monitoring	\$198,896 9.33%	\$1,083,186 14.25%	\$1,624,874 14.28%	\$1,549,761 13.60%
Combined	\$525,333 25%	\$1,489,224 20%	\$2,025,047 18%	\$1,903,363 17%

That's a lot.... in fact
3-5x the cost of data management

If the monitor is going to look at data at all, how
can we help to make this time targeted

And more likely to be productive?

- Dashboard
- Data entry and review
- New data entry from CRFs
- Review queries
- Review reasons
- Review data and metadata
- Show database status
- Run standard reports
- Run batch edit checks
- Topics
- Study help
- Preferences
- Change password

Status Summary for Study Sites

Refresh

Your Study Sites	...
New CRFs (all sites)	71
Pending records	0
Missed records	0
Incomplete records	8
Final records	128
Pending queries	0
Outstanding queries	8
Resolved queries	
Pending reasons	
Rejected reasons	
Approved reasons	

Query Problem <input checked="" type="checkbox"/> All	Count
Missing	6
Illegal	1
Inconsistent	0
Illegible	0
Fax Noise	0
Other	0
Missing Page	0
Overdue Visit	0
EC Missing Page	1
SDV Query	2
Monitor Query	1
Lab Query	1

Introducing multiple Queries and Query Categories

Create SDV category

Double click any table or
Ctrl+1 or select Dashbo



Protocol ABCD-1234:

XYZ Phase 1b/2a Safety, Immunogenicity, and Dose-escalation Study in Adults in South Africa.

Primary Objectives:

To evaluate safety and reactogenicity of XYZ at escalating dose levels,

Query Category Type Map in the DFsetup tool

Set to auto-resolve

DFsetup - QC Problem Type Map - SCDM

View QC Problem Type Map

Code	Label	Auto-Res
1	Missing	Yes
2	Illegal	Yes
3	Inconsistent	Yes
4	Illegible	Yes
5	Fax Noise	Yes
6	Other	Yes
21	Missing Page	No
22	Overdue Visit	No
23	EC Missing Page	No
40	SDV Query	Yes
50	Monitor Query	No
60	Lab Query	No

QC Problem Types

Code 40

Label SDV Query

Auto-Resolve Yes

Sort Order 0

< >

Add Delete Import Search: Revert Save Done

Option 1: The “sister field” method

For some, or all fields, add a check-box next to each field

A SDV query would be added before the monitor sees the form

Check off each SDV queried field and resolve each query

The “sister field” method pros and cons

Pros:

Every field has the capability of allowing SDV

Cons:

Mixing metadata and data

Greatly increase fields in limited space

“Spidey sense” makes me think that it’s not a good idea

Option 2: The “anchor field” method

For some, or all fields, add a SDV query type on each field

A SDV query would be added before the monitor sees the form

Resolve each SDV queried field when SDV complete

The “anchor field” method pros and cons

Pros:

- Every field has the capability of allowing SDV

- No added fields to the database

Cons:

- Not easy to find SDV queries at a glance

- Adding a lot of queries, cluttering query space

Option 3: The “Marginal SDV Fields” method

Designate a single SDV marker field on the page

For example, footer for the page, or margin for a section

Add a SDV query to track these

Resolve when checked

The “marginal SDV field” pros and cons

Pros:

Information can be captured about SDV findings, driving better RBM

Simple for the monitor to understand

Cons:

Doesn't adapt well to SDV changes, not way to track exactly which fields were verified

Do we overuse QCs, now called Queries?

Queries are no longer punitive, but are informational markers

Should another metadata type be created?

Should a new field “type” be created? A button tied to an action?

Create "hidden" fields at the bottom of eCRFs

8 1/2" x 11"

8 1/2" x 13"

8. Outcome

- Unknown
- Other, specify:
- Fatal
- Not recovered/not resolved
- Recovered/resolved
- Recovered/resolved with sequelae
- Recovering/resolving
- Unknown

Version 1.0, 26-MAY-17

SDV:

Problem: Missed Field Data Entry Major Issue Severity: Mild Moderate Severe

Comment:

Reviewer name:

Review date:

Local time:

GMT:

Form:

Visit:

Entry name:

Save m[1->1] Final Incomplete Pending

Last Save: 6/4/2017 17:00:03

AE number