

SGS LIFE SCIENCE SERVICES CLINICAL RESEARCH

**Innovative approach to building an adaptive
trial design in Medidata Rave®**

Joris De Bondt

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WHEN YOU NEED TO BE SURE



- Adaptive Trial Design
 - Planned schedule of patient evaluation for data collection
 - Changes in sampling times
 - Changes in time and event
 - Conclusion of concept
- Demo
- Summary

ADAPTIVE TRIAL DESIGN



WHEN YOU NEED TO BE SURE



■ FDA Guidance for Industry Adaptive Design Clinical Trials for Drugs and Biologics

An adaptive design clinical study is defined as a study that includes a prospectively planned opportunity for modification of one or more specified aspects of the study design and hypotheses based on analysis of data from subjects in the study.

- Study eligibility criteria
- Randomization procedure
- Treatment regimens of the different study groups
- Total sample size of the study
- **Planned schedule of patient evaluations for data collection**
- Primary endpoint
- ...



PLANNED SCHEDULE OF ASSESSMENTS FOR DATA COLLECTION: TRADITIONAL

- Traditional Trial Design
 - eCRF designed to be in-line with the visits and assessments as defined in the study protocol
 - Updates to the protocol result in an amendment of the original protocol
 - Updates to the eCRF are needed
 - New eCRF to be implemented via eCRF Migration Process
 - Turn-around time for implementing a limited change, e.g. adding 1 existing form in a new folder or adding an additional time point on an existing sampling form, is 10 working days

RAVE® MIGRATION PROCESS FLOW



PLANNED SCHEDULE OF ASSESSMENTS FOR DATA COLLECTION: ADAPTIVE

- Adaptive Trial Design
 - Protocols are written from a more flexible, adaptive perspective
 - Visit schedule can be adjusted or additional assessments can be made without the need for a protocol amendment
 - Modifications in the study conduct are allowed and are also clearly pre-defined
 - Changes in sampling times
 - Changes in Time and Event

CHANGES IN SAMPLING TIMES

- E.g. Pharmacokinetics Blood Sample Collection
- Different sampling times in different folders
 - Traditional Trial Design
 - One form per collection of sampling times
 - Additional time point needed: new form to be added to include new time point
 - Adaptive Trial Design
 - One form
 - Time Points completed via Custom Function
 - Additional time point needed: only update to Custom Function is needed
 - Publish Checks job needed to implement
 - Turn-around time for implementation is 2 working days

CHANGES IN SAMPLING TIMES: EXAMPLE

- Adaptive Trial Design
 - PK form build based on code → See paper for code snippet
 - Additional time point needed: only update to Custom Function is needed

#	ANALYTE	Planned Time Point	Was the sample collected?	Reason Not Collected
1	ANALYTE	PRE-DOSE	–	–
2	ANALYTE	END OF INFUSION	–	–
3	ANALYTE	2H	–	–
4	ANALYTE	4H	–	–
5	ANALYTE	6H	–	–



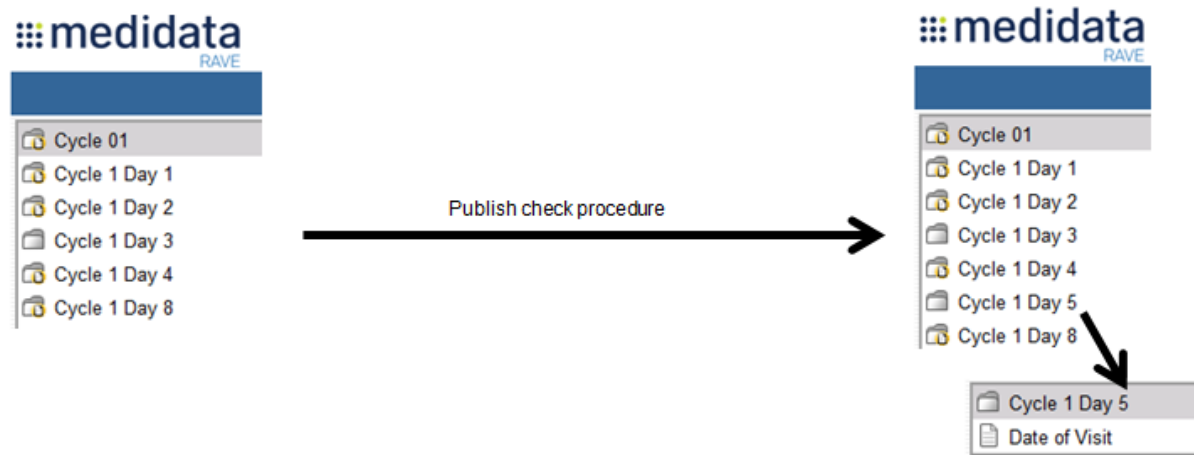
Custom Function

#	ANALYTE	Planned Time Point	Was the sample collected?	Reason Not Collected
1	ANALYTE	72H	–	–

- Original Time and Event: Day 1, Day 2, Day 3, Day 4, Day 8
- We need additional Day 5
 - Traditional Trial Design
 - Additional folder to be added
 - Implementation to be done via eCRF Migration
 - Adaptive Trial Design
 - Possible additional folders are already foreseen in Trial Design
 - Edit Check/Custom Function needed to add existing Form to new Folder
 - Publish Checks job needed to implement
 - Turn-around time for implementation is 3 working days

CHANGES IN TIME AND EVENT: EXAMPLE

- Original Time and Event: Day 1, Day 2, Day 3, Day 4, Day 8
- We need additional Day 5



- Adaptive Trial Design
 - Future-proof eCRF can be built
 - Identify all possible data points that can be influenced by decisions made during the trial
 - All potentially necessary data points will be programmed at the trial start, but will be hidden at Go-Live
- Using this methodology, updates to the trial design can be made available much faster than when using the traditional migration process

DEMO



WHEN YOU NEED TO BE SURE

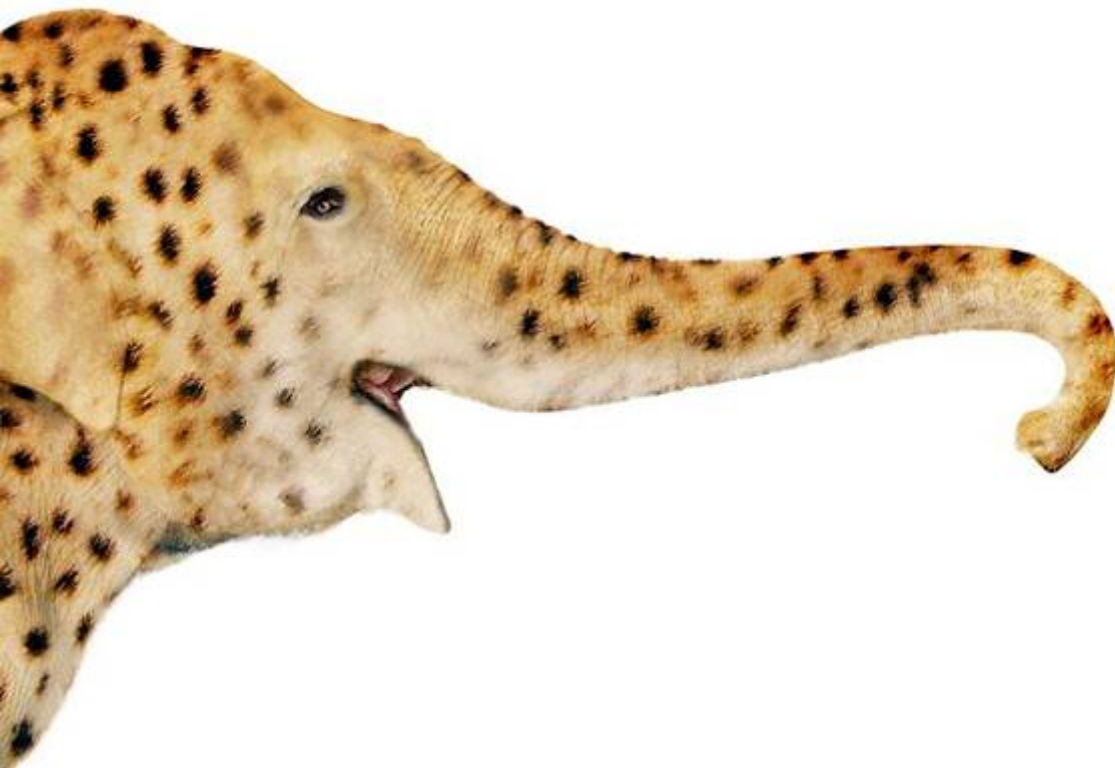


TAKE HOME MESSAGES

- Only applicable to up-front created forms/folders
 - Template Edit Checks/Custom Functions for updates
 - Huge eCRF = Resource intensive
- Involve all stakeholders in the clinical development process to plan the road-map for adaptive trial implementation
- Adaptive trials will be used at scale in our industry moving forward
- Don't forget – it's not just technology! It's also processes and organizational impact

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THANK YOU FOR YOUR ATTENTION



WHERE EXPERIENCE MEETS SPEED

CONTACT US

CLINICAL RESEARCH

lss.info@sgs.com

EUROPE : + : + 33 1 41 24 87 87

AMERICAS : + 1 877 677 2667

www.sgs.com/lifescience

Joris De Bondt

Life Science Services

Head EDC and Data Standards

SGS Belgium NV
Generaal De Wittelaan 19A b5
2800 Mechelen – Belgium
Phone: +32 (0)15 29 93 40
Mobile: +32 (0)473 746477
Fax: +32 (0)15 27 32 50
E-mail : joris.debondt@sgs.com
www.sgs.com/CRO

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