



Handling CRF Design Changes in a Live Environment



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Related paper number DH07

Outline



- Introduction
- Types of design changes in Viedoc
- Common causes of design changes
- Smart ways for setting up a clinical database
- Smart ways for setting up design changes in a trial
- Conclusion

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Introduction



Before Database Go Live

Extensive validation

- Screen design
- Edit checks and calculations
- Study workflow



Database in production

Real life issues force a design change

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Types of design changes in Viedoc

Viedoc is an electronic data collection system

Fully customizable design

- Only for new events
- All changes possible
- Added to the old versions

Design revision

- Update old events
- Applied to all full design versions
- Need approval by site
- Revised data must be reviewed again by the Monitor and Sponsor.

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Common causes of design changes



Why can a design change be necessary?

- Protocol amendment
- CRF setup issues
- Collection of additional source data
- Data entry issues
- Site and/or country specific procedures

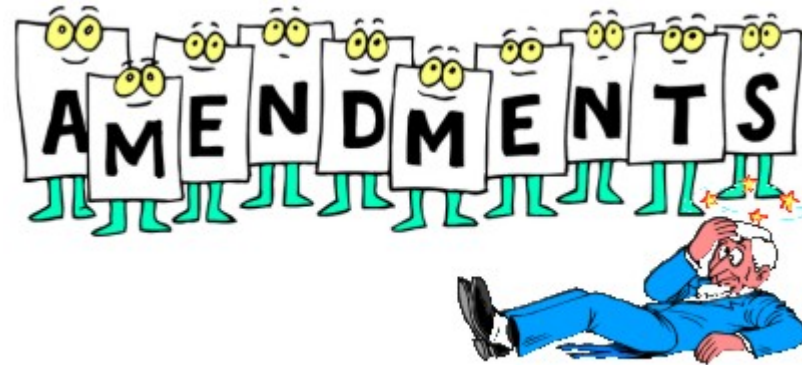


Common causes of design changes



Protocol amendment

- New items to be added in line with the amendment
- Unclear definition of an inclusion criterion





Common causes of design changes

CRF setup issues

- Mistakes in auto-population fields

Incorrect conclusion
on status

Screening score	Nutritional status
0	Malnourished

Populated field could
not be confirmed
as missing

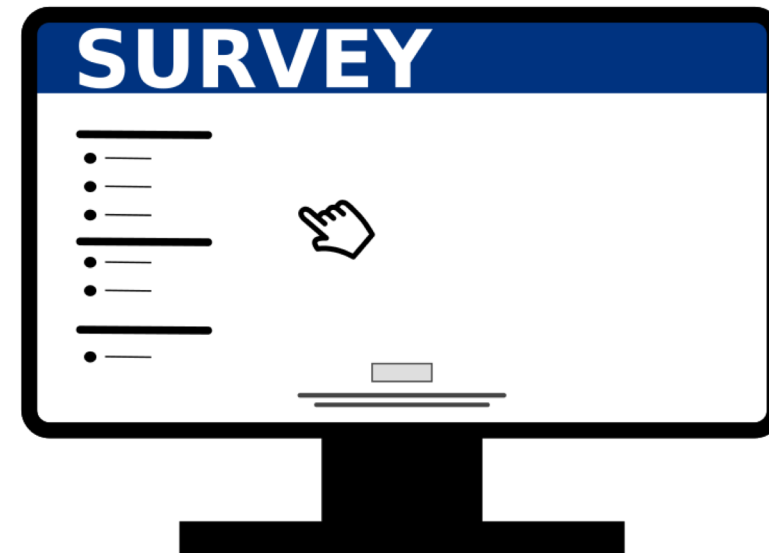
E. Neuropsychological problems	Score
☐ Severe dementia or depression	☐ 0 ☐ 1 ☐ 2
☐ Mild dementia	
☐ No psychological problems	



Common causes of design changes

CRF setup issues (continued)

- Questionnaire structure in a different country
 - Order of questions different
 - Order of replies different





Common causes of design changes

CRF setup issues (continued)

- Code list differs between old and revised design
- An extra tab was added in export value (represented as →) by mistake

Old design		Revised design	
Text on CRF	Export value	Text on CRF	Export value
0-2 episodes	0-2 episodes	0-2 episodes	0-2 episodes→
3-5 episodes	3-5 episodes	3-5 episodes	3-5 episodes→



Common causes of design changes

Collection of additional source data

- Backup study product dispensing added for all subjects in eCRF

Was assigned study product dispensed during this visit?

☐ Yes ☐ No

Product number of dispensed study product

Was backup study product dispensed during this visit?

☐ Yes ☐ No

Product number of backup study product

NEW data

Extra!

Common causes of design changes



Data entry issues

- AE form could not be saved due to edit check firing incorrectly
- AE End Date UNK-Feb-2018
- SAE End Date 14-Feb-2018
- Message SAE End date is not on or before the AE End date.
- Design change to choose:
 - Edit check improved
 - Form can be saved despite of error



Common causes of design changes

Site and/or country specific procedures

- New role for a specific country
- Data entry of diaries (Data entry role)
- Data entry of stool sample data and resolving queries (extra task)

The screenshot shows a user role configuration interface. On the left, the 'Name' field is 'Study Nurse Lab' (highlighted with a red box) and the 'Status' is 'ON' (toggle switch). Below, the 'Description' field contains the text 'Study Nurse for Austria who collects and handles stool samples'. On the right, the 'Special' section has three checked options: 'User can only view form data (this overrides all edit permissions)', 'Medical coding', and 'View reference data'. At the bottom, the 'CRF Rights' section (highlighted with a red box) has one checked option: 'Add/update subject/event/form data and query answers'.



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Smart ways for setting up a clinical database



Making the design stable and resistant to future changes

- Create a library of standardised CRFs and edit checks
- Use hidden markers for site- and country specific items
- Align the CRF design with the study procedures
- Keep track of design changes
- Proper testing of the CRF
- Test all thinkable scenarios that may occur in the study



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Smart ways for setting up design changes in a trial



How can we keep the number of design changes minimal?

- Participate in protocol review
- Ensure high quality of the CRF at study start
- Avoid making esthetical changes
- Create awareness of the risks of design changes
- Timing of design changes
- Implement multiple updates in one design change
- Use CRF instructions and training to clarify issues

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Conclusion

Updates to a live clinical trial database can be less of a burden by:

- Adequate review of the study protocol by different clinical functions
- Use of standardized CRFs
- Proper testing of the eCRF which includes all scenarios that may occur in the study

However, design changes during a study cannot entirely be avoided. In case an update of a live database is required, it should be handled efficiently and smart as described in our DH07 paper.

Thank you! Questions?



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