Fun With Plate Markers

Concept and Use of the Module: Plate Markers

By: Richard Veerman, Factory CRO
Who is Factory CRO?

- CRO that is specialized in medical devices
- 40+ in-house employees: 5 DM, 20 in-house CRA’s, 5 Medical Writers
- Expertise
  - Our CEO and CMO are Medical Doctors who founded Factory CRO in 1988
  - 25+ years experience in Medical Device trials including all study types, indications, patient population size etc.

- Provide complete range of services
  - Consultancy
  - Regulatory
  - Clinical Trial Services
  - Data Management (incl. SDTM)
  - Statistics (incl. ADaM)
  - Medical Writing

- Global coverage
  - Offices based in the USA, Europe and the Caribbean
  - Branches all over the globe; including South-America, Australia and Canada

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Who are we?

- Richard Veerman, Project Manager DM
  - Msc in Human Movement Science
  - +/- 4 years DM experience with iDataFax / DFDiscover
  - 2nd DFUG meeting
  - Based in Bilthoven, The Netherlands

- Pascal Groenen, COO
  - PhD in Epidemiology
  - +/- 15 years DM experience with iDataFax / DFDiscover
  - 13th DFUG meeting
  - Based in Bilthoven, The Netherlands

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Presentation Topic: plate markers

• Concept
  o What was the need?
  o What did we come up with?

• Use
  o Data review workflow: page retrieval tasks
  o CRF review statement e-signature module
  o Study status

• Edit Check Functionalities
Concept: the need

- DM & CRA work in parallel (eCRF page-by-page)
- Struggle to identify DM/CRA review status based solely on Plate Level & Status
- Desire to get more plate information including:
  - DM review status
  - CRA review status
  - Time stamps for data entry & review
- Simplify plate level constructions & get more information
Concept: the answer

• We needed three things:
  o 1. Include ‘plate marker’ data fields
  o 2. ECs to conditionally fill the Marker Fields
    ▪ Based on user role & save option selected
    ▪ Fully automated
  o 3. Ability to search through modules instead of plates*

* Thanks to the 2014 version updates
Use: data review workflow

• Autocomplete review status CRA/DM upon saving the plate
  o Options for DM and CRA tracking fields
    ▪ Not Done (New)
    ▪ Approved
    ▪ Disapproved
    ▪ Updated
    ▪ NA
  o Status independent of plate level
  o If ‘Approved’ or ‘Disapproved, change to ‘Updated’ upon site update
  o Ability to mark certain screen failure plates ‘NA’ for CRA
  o CRA’s are unable to save as incomplete if there are no open queries
  o Auto-save to level 4 when both CRA and DM have status ‘Approved’
  o Autocomplete time stamp for First Creation (site), Last Modification (site), First DM/CRA review

• Define page retrieval task that searches module MARKERS
  o Unable to use Data View → use Define Views in List View
  o Define List View that searches for DM or CRA status field in module MARKERS that is “Not Done” or “Updated”
  o Check ‘Criteria: new task’ so that all records in the List View are in a task set
  o Select the defined to-do list in ‘By View’ to retrieve a list of all records that are new or updated
  o Double-click on a record to link to the Data View task set
Use: CRF review statement e-signature

• How to ensure that the PI signature is > last eCRF modification & approve in batch (1 signature per patient)?
  o Include a plate called eCRF Review Statement
  o Use time-stamps in module Markers
  o Use ECs to check if signature datetime is before last modification datetime & query for re-signing

• Steps in eCRF completion progress per patient (fully automated by Edit Checks):
  o Hide eCRF Review Statement during FU period
  o Show in patient binder if Study End is completed
  o Query & allow sign-off if:
    ▪ Patient has no outstanding queries
    ▪ Study end is completed
  o Once signed-off, re-query for sign-off if: modification datetime of any record > datetime signature Review Statement
  o Upon re-signing, auto-resolve query
**Use: Study status**

- Use SAS to display data entry & review metrics in status reports in total # of records and in percentage of total records.
DM status: MADMSTAT

Plate enter
- MA_DTM

Plate Exit
- MA_STAT
- MA_NA

- MA_DTM: completes datetime stamps using DFMODIFY and DFCREATE
- MA_STAT: conditionally completes CRA and DM status and user (dfwhoami) based on role (dfrole) and save option (dfstatus) +
  - Re-saves the page to re-run MA_DTM (dftrigger): this is to complete the current (post-save) DFMODIFY
    - To prevent “Last Modification” date to update on plate entry: use MALCMMARK to complete datetime only if set to code=2 (In Progress). MALCMMARK is set to 2 by MA_STAT (plate exit), and set back to 1 by MA_DTM after datetime completion (plate entry)
  - Check for open queries (dfunresqc) and prevent CRA from saving a plate as incomplete if there are no open queries (dfwarning + dfstay)
  - Auto-save to level 4 if DM & CRA both approve (dfpref)
- MA_NA: mark CRA field for certain plates Not Applicable upon study specific condition
Edit Check Functionalities

• First setup & exploration Marker module: 15 – 20 hours

• Implementation in new studies of Marker & ESIG module: 10 – 15 minutes
Questions?