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Single Day Event

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Speaker Information

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Biography:	10 years experiences in clinical data management field. I joined dMed in 2017, I and my team are responsible for clinical data collection mechanisms setup and system related processes enablement. I have solid knowledge about all mainstream clinical EDC systems. Prior to dMed, I worked for MNC, local and international CRO companies.

Adapt to Dynamic Trial Design in Medidata Rave

An eCRF is always designed to be in-line with the visits and assessments as defined in the study protocol. Traditionally, protocols were written rigidly and therefore everything mentioned in the original protocol was fixed in the eCRF.

Medidata Rave - is an industry-leading electronic data capture system, it provides both intuitive and sophisticated interfaces and allows database builders to create robust data collection instruments.

In this session we will share some cases by using the Rave Custom Functions to realize dynamic eCRF design to meet customized trial design requirements in Medidata Rave. The Adaptive design could save time and budget.

Adapt to Dynamic Trial Design in Medidata Rave

Case 1:

Project A is an phase III oncology study.

There are 36 planed Visits, and additional Visits maybe needed in some special .

If we design the Database in a traditional way - build fixed folders for the planed Visits.

A Database amendment is be needed if some subjects need additional Visits, and this require a migration process in Rave.

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Case 1 – solution:

A dynamic with Custom Function could be programmed in study, and this CF could add the specified folder repeatedly with no limit.

Then we could build one folder in Rave, and program this kind of dynamic.

In Rave EDC, if the next Visit will occur, the site user submit the trigger point, and a new folder could be added out.

No Rave migration process is needed if some subjects need additional Visits more than 36.

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Case 1 – Part of the CF code

```
// do nothing when the folder is not what we need
if (current_OID != firstTrigger_OID && current_OID != rptCycle_OID)
    return null;

// calculate the total number of repeat cycles
Instances all_ins = subj.Instances;
Instances Cycles = new Instances();
int count = 0;
for (int i = 0; i < all_ins.Count; i++)...
// Add matrix only when input_DP is yes and avoid generating unexpected cycle when input_DP is ticked YES then NO then YES and so on
if (input_DP.Data == NextcycleY && input_DP.IsObjectChanged && (current_OID == firstTrigger_OID && currRepeatNo > (count - 1) || current_OID =
// inactivate folders when selecting NO in the last fixed visit, which is the first trigger folder
if (input_DP.Data == NextcycleN && current_OID == firstTrigger_OID && count == 1 && Cycles[0].EntryStatus == EntryStatusEnum.NoData)
    Cycles[0].Active = false;
else if (input_DP.Data == NextcycleY && current_OID == firstTrigger_OID && count == 1 && Cycles[0].Active == false)
    Cycles[0].Active = true;

// inactivate folders when selecting NO in the "CYCLE" folder before the last "CYCLE" folder, which are repet cycle folders
if (input_DP.Data == NextcycleN && count > 1 && current_ins == Cycles[count - 2] && Cycles[count - 1].EntryStatus == EntryStatusEnum.NoData)
    Cycles[count - 1].Active = false;
else if (input_DP.Data == NextcycleY && count > 1 && current_ins == Cycles[count - 2] && Cycles[count - 1].Active == false)
    Cycles[count - 1].Active = true;

return null;
```

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Case 2:

Project A is in conduct period.

There is a protocol amendment, and per the new protocol version 2.0 the PK sample time points is reduced from 4 to 3 in a fixed logline form.

If the subject is enrolled per protocol V2.0, then the PK form should only have 3 time points.

The site have subjects that will be enrolled to study per protocol V2.0, the study team want to have the DB update ASAP.

Rave migration process may take about 10 days.

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Case 2 – solution:

A dynamic with Custom Function could be programmed in study, and this CF could inactivate the 4th logline in the PK form if meet the requirements.

Then only the new dynamic is needed, no need to add a new PK form with 3 fixed logline.

The Publish Checks tool is designed to publish changes to edit checks, custom functions, or derivations within an existing Rave CRF version outside of the migration process.

The typical turn-around time for going through a complete publish check process is 3 working days.

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Case 3:

Project B is an extension trial of Project A.

Subject in Project A can continue in Project B when certain conditions are met and when they give their informed consent.

To avoid the double entry of data in extension study, the study team want to have the existing data from parent study being transferred to extension study.

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Case 3 - solution:

Pre-Requisites of parent Study Data:

- Data must be complete
- No Open Queries
- CRF signed by investigator
- CRF or Logline must be soft locked or Frozen by Data Manager

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Case 3 - solution:

Requirements in Target study:

- The fields where the data transfer has to be done, those fields will be in frozen status in order to avoid data entry by site. (handled via CF)
- A Trigger checkbox to call the Data Transfer CF.
- Custom Function
- Data Transfer – Data Manger role

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Case 3 - solution:

A set of CFs could be programmed in the target project:

- First the subject number should be same in Target study and parent study.
- The Site Number and Subject Name are unique in parent study.
- When the Site Number and Subject Number are same in Target study and Parent study only Data will be transferred.
- Transfer is done from DEV to DEV, UAT to UAT for testing and PROD to PROD env.
- Once the conditions are satisfied in Parent study, when the Data Transfer check box is checked in target study, the data will be transferred.

Q&A

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