



Formation Bio

Agenda

Introduction

Define edc, highlight the problem

veeva

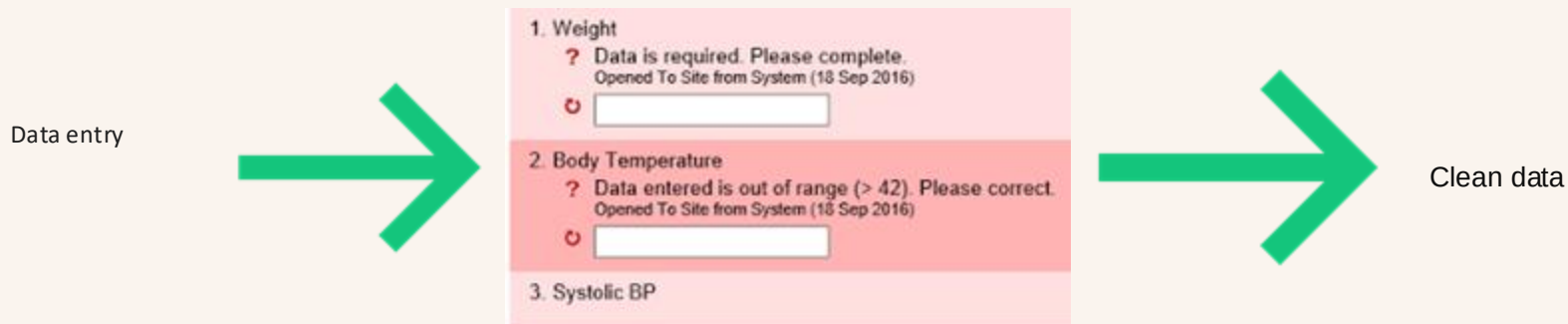
medidata



viedoc™

The Importance of Edit Checks

- Define edit checks as **the first line of defense against bad data**
- Explain how **robust edit checks** improve data integrity, patient safety, and efficiency



The Complexity of Edit Check Programming

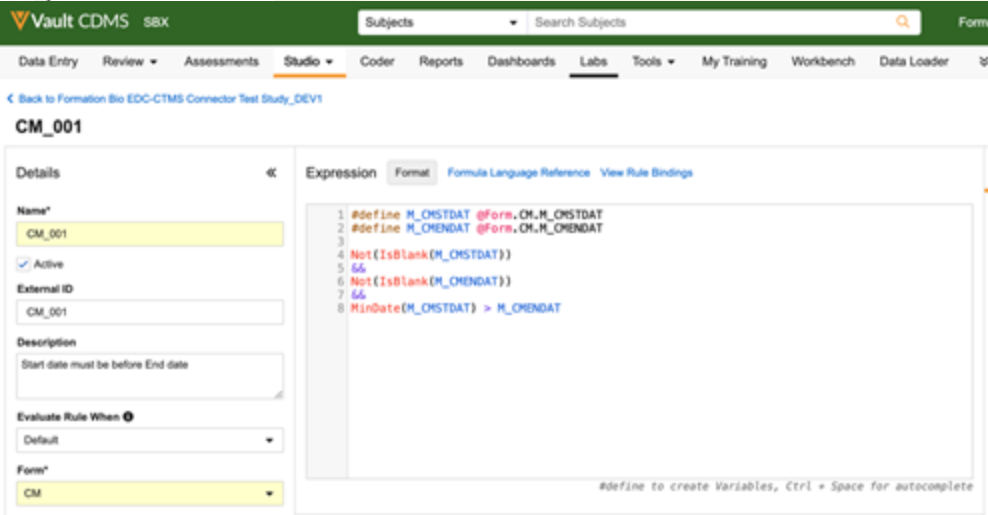
- 

```
UAT_CF1 CM
ActionFunctionParams afp = (ActionFunctionParams)ThisObject;
DataPoint dpt_Action = afp.ActionDataPoint;

Subject sbj = dpt_Action.Record.Subject;

string folderOID = dpt_Action.Record.DataPoints.FindByFieldOID("UAT_FOLDER").Data;
string formOID = dpt_Action.Record.DataPoints.FindByFieldOID("UAT_FORM").Data;
string fieldOID = dpt_Action.Record.DataPoints.FindByFieldOID("UAT_FIELD").Data;

DataPoints dpts = CustomFunction.FetchAllDataPointsForOIDPath(fieldOID, formOID, folderOID, sbj, false);

string datapageID = "";
if (dpts.Count > 0) {
    datapageID = dpts[0].Record.DataPage.ID.ToString();
}
```
- 

Vault CDMS SBX

Subjects Search Subjects

Data Entry Review Assessments **Studio** Coders Reports Dashboards Labs Tools My Training Workbench Data Loader

< Back to Formation Bio EDC-CTMS Connector Test Study_DEV1

CM_001

Details

Name* CM_001

☒ Active

External ID CM_001

Description Start date must be before End date

Evaluate Rule When Default

Form* CM

Expression

```
1 #define M_CHSTDAT @Form.CH_M_CHSTDAT
2 #define M_CHENDAT @Form.CH_M_CHENDAT
3
4 Not(IsBlank(M_CHSTDAT))
5 &&
6 Not(IsBlank(M_CHENDAT))
7 &&
8 MinDate(M_CHSTDAT) > M_CHENDAT
```

#define to create Variables, Ctrl + Space for autocomplete

Development of Edit Checks

Manual Process

Not priority for study go live



Using AI

Ready for go live

Time consuming



Fast

Steep learning curve



AI does the learning

How the AI Model Works

- **Inputs:** Study Design Specification (SDS)
- **Process:** AI interprets SDS, applies rules, and generates edit checks
- **Outputs:** Pre-programmed edit checks, ready for implementation

Knowledge:

-  Comparison Rules.pdf
-  Creating Rules (V2).pdf
-  Cross-form Derivations.pdf
-  Mapping Casebook Variables.pdf
-  Rule Design Properties.pdf
-  Sending Email Notifications with Rules.pdf
-  Tips & Best Practices for Rules.pdf

Input: Study Design Specification (SDS, contains all forms and the visit schedule of a specific trial build)

Key Benefits of Automation

Faster Study Start-Up: Saves time during edit check programming

- **Better Data Quality:** Ensures no critical checks are missed
- **Cost Savings:** Reduces manual work and rework
- **Scalability:** Works across multiple EDC systems



Conclusion & Next Steps

Summary of key takeaways

- The future of AI in clinical data management
- Call to action: **How can study teams leverage AI today?**
- (Optional) Q&A