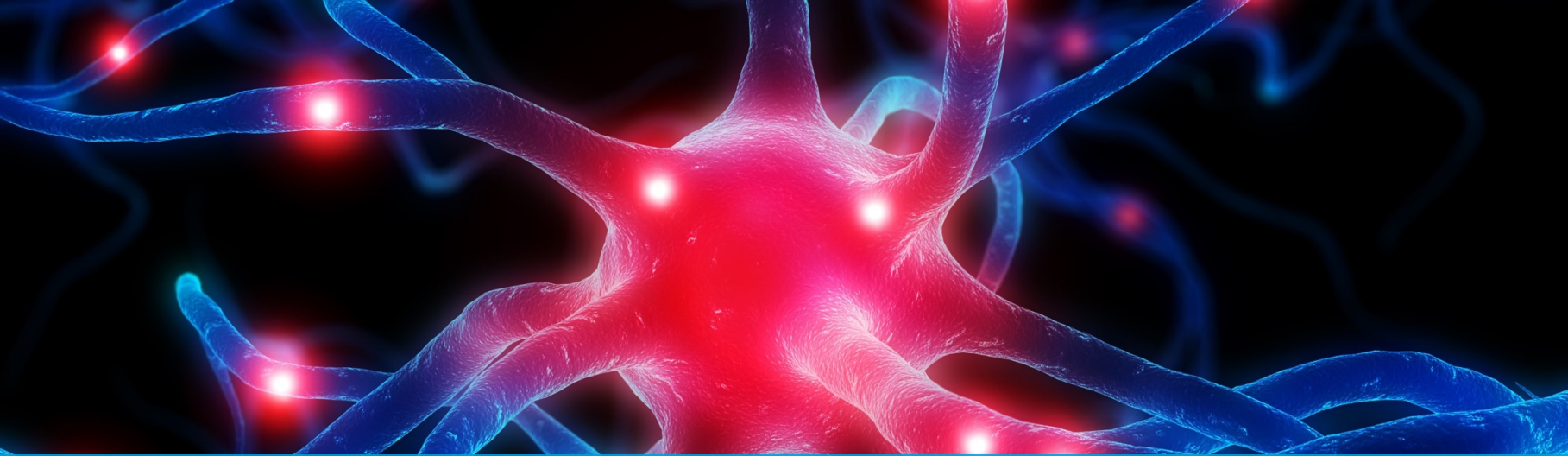




Novel eCRF study template to support adaptive design studies in Medidata Rave

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Integrated Data Analytics and Reporting
Nov 2020

Active neuron

The opinions in this presentation are my own and do not necessarily reflect the views and policies of J&J



Agenda

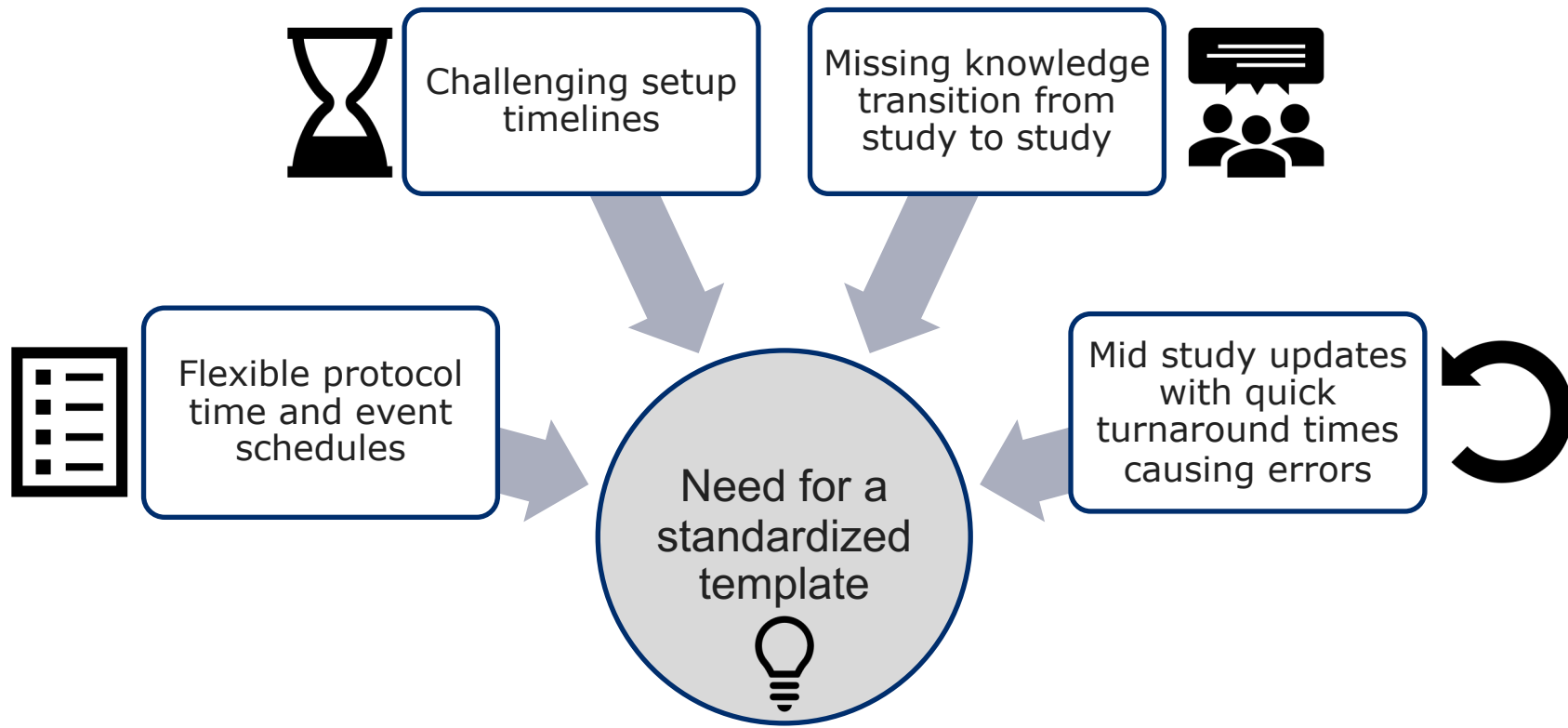
- 1 Flexible template philosophy
- 2 Technical deep dive
- 3 Read out and evaluation
- 4 Summary
- 5 Team acknowledgement | Q&A



Flexible template philosophy

Skin cells at 20x magnification

Problem statement



Background

Handling challenging flexible protocols



eCRF design needs to be:

- Flexible
- Adaptable
- Easy to implement and maintain
- Reusable



Up till now, flexible design protocols posed challenges:

- lengthy setup timelines
- Intricate migrations

Flexible template philosophy



Purpose

To develop a template for flexible design studies that will allow for adaptive dynamic visit structures.

Requirements

Easy to implement standardized visit to visit dynamics

Ability to switch dosing schedules between dosing periods

*Ability to adjust the number of visit days within treatment period /
Dosing period*

Ability to add assessments forms in a flexible manner

Design considerations



Maximize re-usability of code and roll back principle when data entry errors are made on trigger questions



Minimize the number of updates needed to make the code work (i.e, generalize as much as possible)



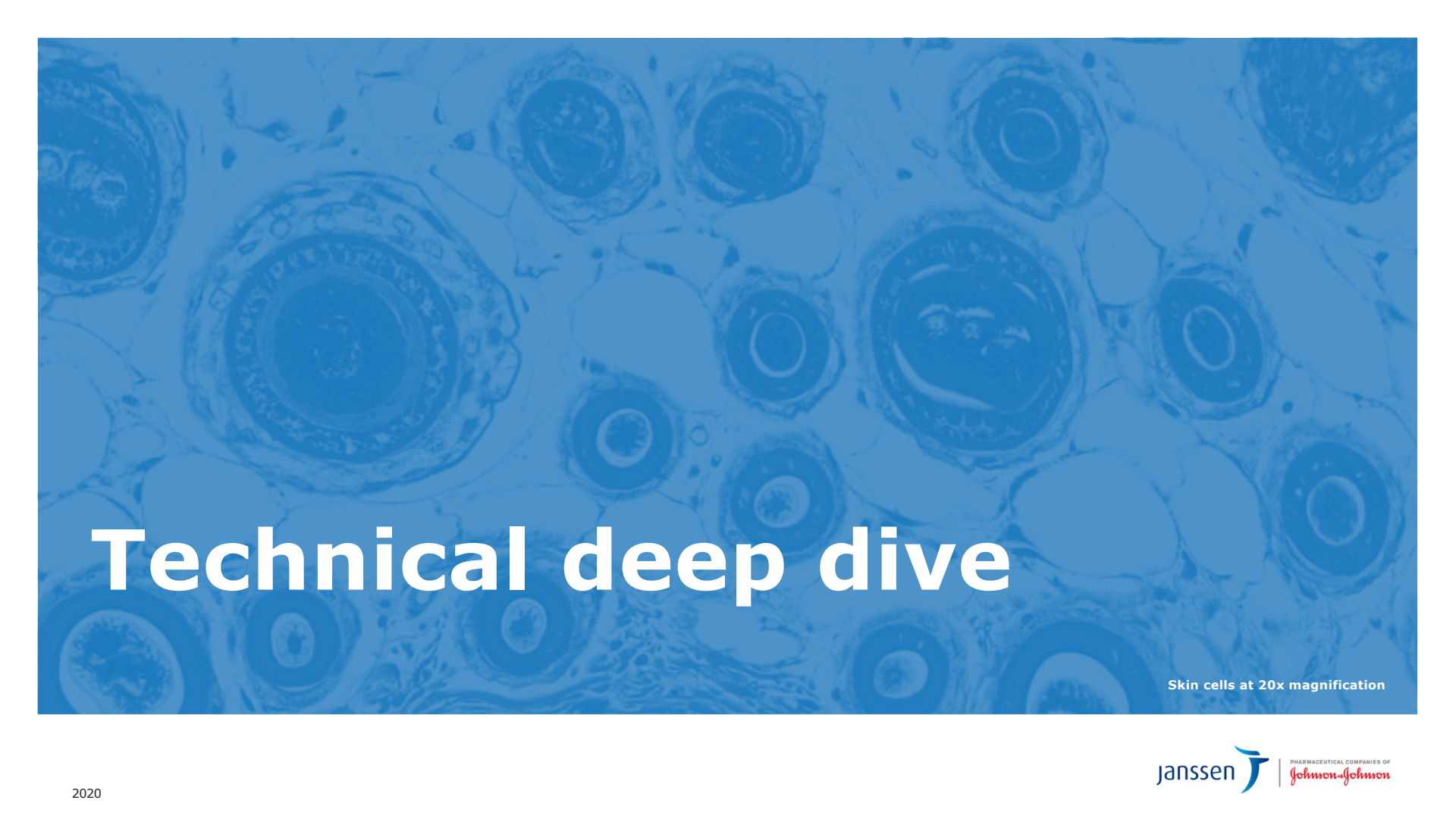
Allow for adaptability without the need to make updates to the study setup



Keep everything contained within the study



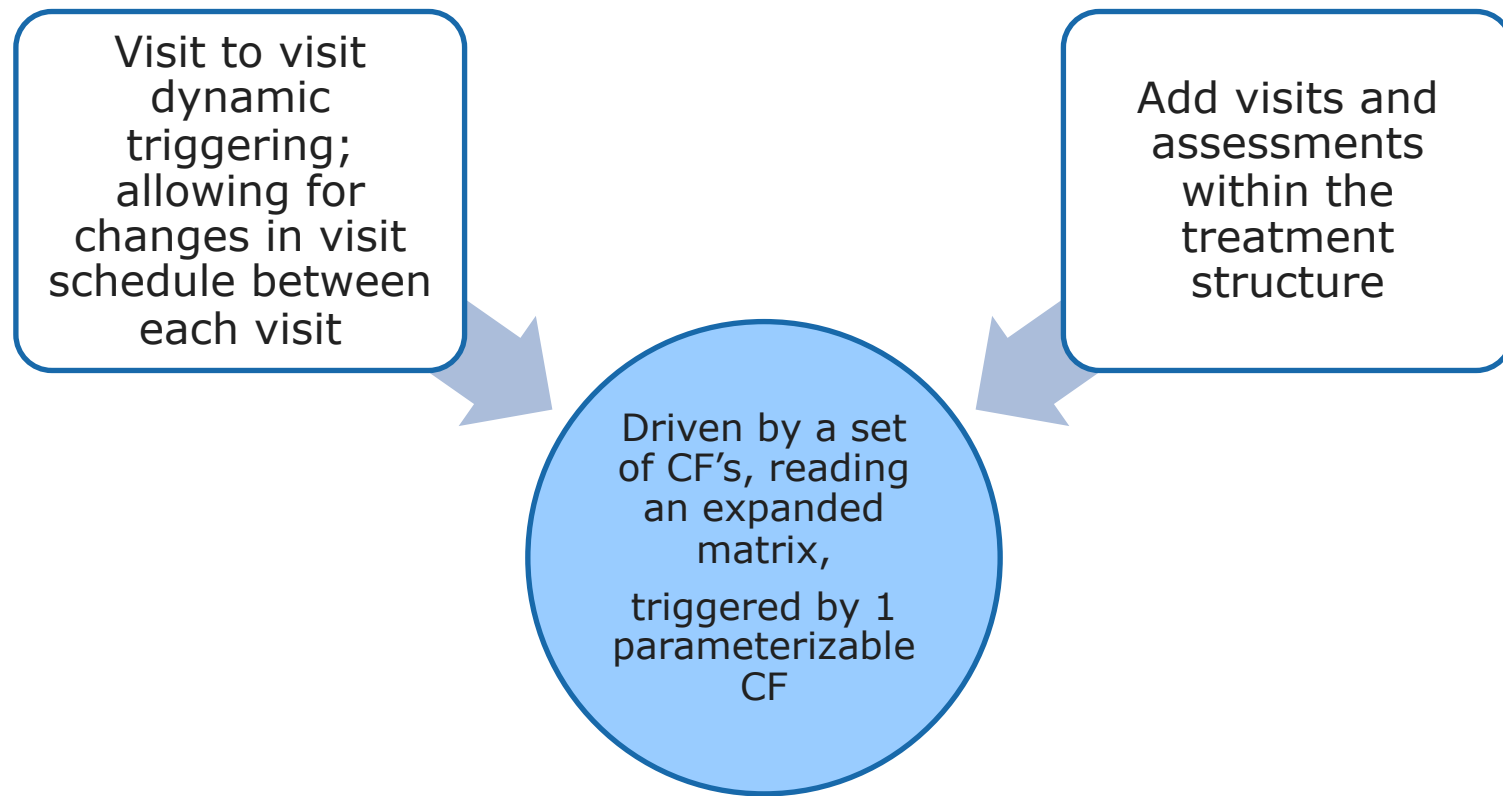
Do not impact integration requirements and Rave requirements



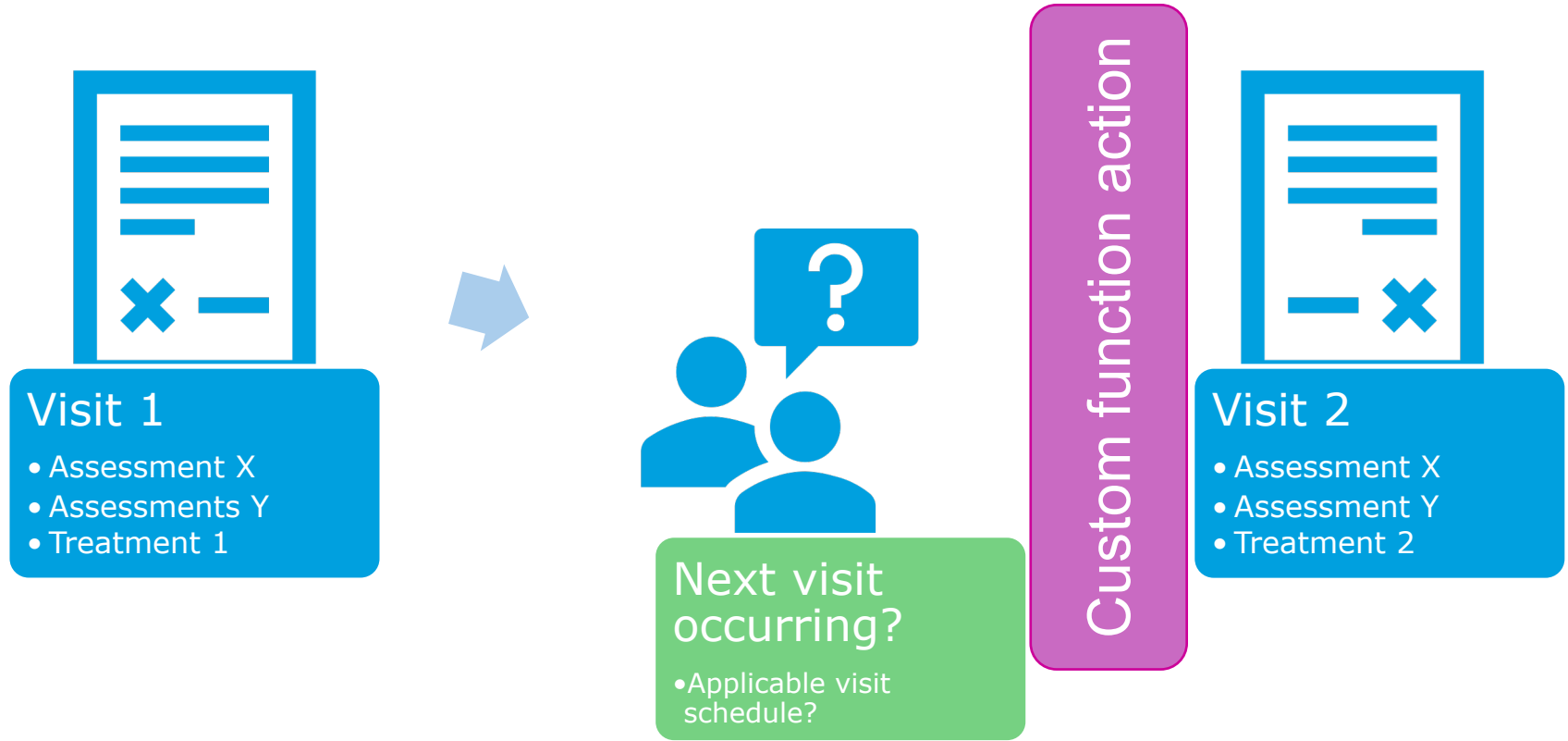
Technical deep dive

Skin cells at 20x magnification

Dual flex template focus



Visit to visit triggering



Features of the custom function

- All custom functions are **generic** and managed via 1 Parameters custom function (CF)

Name

▶ CF_FX_ADD_CYCDAY_CYCLEDAY_AddDayFolder

▶ CF_FX_ADD_CYCDAY_DSL

▶ CF_FX_ADD_PAGENUMB_DSL

▶ CF_FX_AddCycleDays

▶ CF_FX_AddFolder

▶ CF_FX_AddForm

▶ CF_FX_AddScheduledVisits_RETREATMENT

▶ CF_FX_ASSESSMENTNOW

▶ CF_FX_NEXTC_AddCycleDays_NextCycle

▶ CF_FX_NextVisit

▶ CF_FX_Parameters

▶ CF_FX_PopulateAssessmentForm

This CF needs to be adapted trial specifically and is the input for all other custom functions

Features of the custom function

- Parameter custom function: update trial specific items such as visit schedules

```
////////////////////////////////////  
// Visit schedule Matrix OID (dataRequest == "VSCHED")  
////////////////////////////////////  
Hashtable vschedTable = new Hashtable();  
  
vschedTable.Add("A", "IVBW");  
vschedTable.Add("B", "IVQ2W");  
vschedTable.Add("C", "IVW");  
vschedTable.Add("D", "SCBW");  
vschedTable.Add("E", "SCQ2W");  
vschedTable.Add("F", "SCW");  
//vschedTable.Add(codedValue, matrixOID);  
#endregion CF_FX_NEXTC_AddCycleDays_NextCycle  
  
#region CF_FX_NextVisit  
////////////////////////////////////  
// Set possible folderOIDs for starting cycle folder (dataRequest == "STARTING_FOLDEROID")  
////////////////////////////////////  
ArrayList arrayFolderOIDs_startingCycle = new ArrayList()  
{  
    "SCREEN", "PRIMING"  
}  
;  
;
```

Update the study specific schedule names ~ match with matrices names

Expanded matrices

- Every visit structure is contained in 1 matrix

Architect 00NAS Oncology ED Template Onco ED Template Final Matrices						
	Name	OID	Allow Add	Max	Edit	Folder Forms
☐	Default Matrix	DM	☐	0	☒	▶
☐	Intravenous BiWeekly	IVBW	☐	0	☒	▶
☐	Intravenous Every2Weeks	IVQ2W	☐	0	☒	▶
☐	Intravenous Weekly	IVW	☐	0	☒	▶
☐	Priming	PRIMING	☐	0	☒	▶
☐	Retreatment	RETREATMENT	☒	1	☒	▶
☐	Screening	SCR	☐	0	☒	▶
☐	Subcutaneous Biweekly	SCBW	☐	0	☒	▶
☐	Subcutaneous Every2Weeks	SCQ2W	☐	0	☒	▶
☐	Subcutaneous Weekly	SCW	☐	0	☒	▶
☐	Subsequent doses	SD	☒	999	☒	▶

➔ Only minimal amount of matrices required to set up the study

- It is the custom function what will look at the current visit and will scan for the next visit to add the correct visit structure

Expanded matrices

Custom function scanning

00NAS Oncology ED Template																									Onco ED Template Final					Matrices			Intravenous Every2Weeks				
	Subject	Screening	Priming Visit	Dose 1	Dosing 1 day	Dosing 1 + 24h	Dosing 1 + 36/48h	Dosing 1 + 72h	Dosing 1 + 96h	Dosing 1 + 120h	Dosing 1 + 144h	Dosing 1 + 168h	Dosing 1 + 192h	Dose 2	Dosing 2 day	Dosing 2 + 24h	Dosing 2 + 36/48h	Dosing 2 + 72h	Dosing 2 + 96h	Dosing 2 + 120h	Dosing 2 + 144h	Dosing 2 + 168h	Dosing	Screening to end of study	Retreatment												
Date of Visit					✓	✓									✓																						
Demographics																																					
Inclusion/Exclusion Criteria																																					
General Medical History																																					
ECOG Performance Status				✓										✓																							
Neurological Exam (Screening)																																					
Vital Signs (Timepoints, SC)																																					
Hematology				✓	✓									✓																							
Coagulation				✓	✓									✓	✓																						
Urinalysis																																					
Fresh Tumor Biopsy Collection																																					
Baseline Bone Scan [PCWG3]																																					
Study Drug Infusion Administration for JNJ-63898081				✓										✓																							
Disease Evaluation Assessments																																					
PSA Results																																					
Adverse Events Summary																																					
Adverse Events/Serious AEs																																					
Concomitant Therapy Summary																																					

Prerequisites of the custom function

- Folders are set up in the correct order (on how they need to appear)
- OID are 'fixed', name can be adapted trial specifically



Architect 00NAS Oncology ED Template Onco ED Template Final Folders			
	Name	OID	Parent Folder
	Screening	SCREEN	No Parent Folder
	Priming Visit	PRIMING	No Parent Folder
	Dose 1	C1	No Parent Folder
	Dosing 1 day	C1D1	Dose 1
	Dosing 1 + 24h	C1D2	Dose 1
	Dosing 1 + 36/48h	C1D3	Dose 1
	Dosing 1 + 72h	C1D4	Dose 1
	Dosing 1 + 96h	C1D5	Dose 1
	Dosing 1 + 120h	C1D6	Dose 1
	Dosing 1 + 144h	C1D7	Dose 1
	Dosing 1 + 168h	C1D8	Dose 1
	Dosing 1 + 192h	C1D9	Dose 1
	Dose 2	C2	No Parent Folder
	Dosing 2 day	C2D1	Dose 2
	Dosing 2 + 24h	C2D2	Dose 2
	Dosing 2 + 36/48h	C2D3	Dose 2
	Dosing 2 + 72h	C2D4	Dose 2
	Dosing 2 + 96h	C2D5	Dose 2
	Dosing 2 + 120h	C2D6	Dose 2
	Dosing 2 + 144h	C2D7	Dose 2
	Dosing 2 + 168h	C2D8	Dose 2
	Dosing	CD	No Parent Folder
	Screening to end of study	SCRDS	No Parent Folder
	Retreatment	RETREATMENT	No Parent Folder

1. Visit to visit dynamics

SCREENING TO VISIT 1

00NAS Oncology ED Template 105_DEV 26022020 Screening Treatment Assignment Information

Subject: 26022020
Page: Treatment Assignment Information - Screening?

Study Part
Priming

Assigned dosing schedule for Dose 1

Will preplanned COHORT intracycle dose reduction be applied for this subject?

Version of the protocol signed at consent

- ☐ Intravenous BiWeekly
- ☐ Intravenous Every2Weeks
- ☐ Intravenous Weekly
- ☐ Subcutaneous Biweekly
- ☐ Subcutaneous Every2Weeks
- ☐ Subcutaneous Weekly

Dose schedule → input for correct visit schedule to be triggered
(= input for the CF)

1. Visit to visit dynamics

VISIT TO VISIT

Next dose selection form to go from one dosing period to the other + switch in dosing schedule

The screenshot shows the 'Next Dose Selection (Dose)' form for Subject 9983. The form includes a sidebar with a list of options, including 'Next Dose Selection (Dose)'. The main content area contains the following text:

Subject: 9983
Page: **Next Dose Selection (Dose) - Dose 1** ?

Is the subject continuing to the next dose? Yes ☒

If Yes, which dosing schedule will the subject follow in the next dose?

Please specify the protocol version, applicable for the next dose

[Printable Version](#) [View PDF](#) [Icon Key](#)
CRF Version 17176 - Page Generated: 13 Mar 2020 13:07:03 Romance Standard Time

The dropdown menu is open, showing the following options:

- Intravenous BiWeekly
- Intravenous Every2Weeks
- Intravenous Weekly
- Subcutaneous BiWeekly
- Subcutaneous Every2Weeks
- Subcutaneous Weekly

To go from one dosing period to the other one

Choose the applicable schedule for next dose

2. Adding additional visit days and assessments

Add an additional visit day which was not predefined upfront in the schedule (not using an 'add event' functionality)

The screenshot displays the Janssen Oncology ED Template interface. The top navigation bar includes tabs for '00NAS Oncology ED Template', '104_DEV', '9983', 'Dose 1', and 'Add Dose Day'. The left sidebar lists various assessment categories, with 'Add Dose Day' highlighted. The main content area shows a form for 'Subject: 9983' and 'Page: Add Dose Day - Dose 1'. A table with columns 'Cycle Day' and 'Other, Specify' is visible, with a row for '1'. Below the table, there is a link to 'Add a new Log line' and an 'Inactivate' button. A blue box highlights the table area, and a blue arrow points from the 'Add Dose Day' option in the sidebar to this box. The bottom of the form shows 'CRF Version 17176 - Page Generated: 13 Mar 2020 13:31:03 Romance Standard Time' and 'Save' and 'Cancel' buttons.

00NAS Oncology ED Template | 104_DEV | 9983 | Dose 1 | Add Dose Day

Dose 1

- Dosing 1 day
- Dosing 1 + 24h
- ECOG Performance Status
- Hematology
- Coagulation
- Study Drug Infusion Administration for JNJ-63898081
- Neurological Exam
- Vital Signs (Timepoints)
- Vital Signs, Weight only
- Add Dose Day**
- Next Dose Selection (Dose)

Subject: 9983
Page: Add Dose Day - Dose 1

Cycle Day	Other, Specify
1	

Add a new Log line Inactivate

CRF Version 17176 - Page Generated: 13 Mar 2020 13:31:03 Romance Standard Time

Save Cancel

2. Adding additional visit days and assessments

Within an existing dosing day or a new dosing day, the assessments form allows for triggering of additional forms

00NAS Oncology ED Template

104_DEV

9983

Dose 1

Dosing 1 day

Assessments

Dosing 1 day

Date of Visit

Hematology

Coagulation

Vital Signs (Timepoints)

Assessments

CRF History

9983 - Assessments

9983 - Date of Visit

9983 - Add Dose Day

9983 - Next Dose Selection (Dose)

9983 - ECOG Performance Status

9983 - Next Priming

Subject: **9983**

Page: **Assessments - Dosing 1 day**

#	Form Name	Total number of pages
1	NEUROLOGICAL EXAM (SCREENING)	1
2	HEMATOLOGY	2
3	COAGULATION	3
4	URINALYSIS	4
5	FRESH TUMOR BIOPSY COLLECTION	5
6	DISEASE EVALUATION ASSESSMENTS	6
7	PSA RESULTS	7
		8
		9
		10

[Printable Version](#) [View PDF](#) [Icon Key](#)

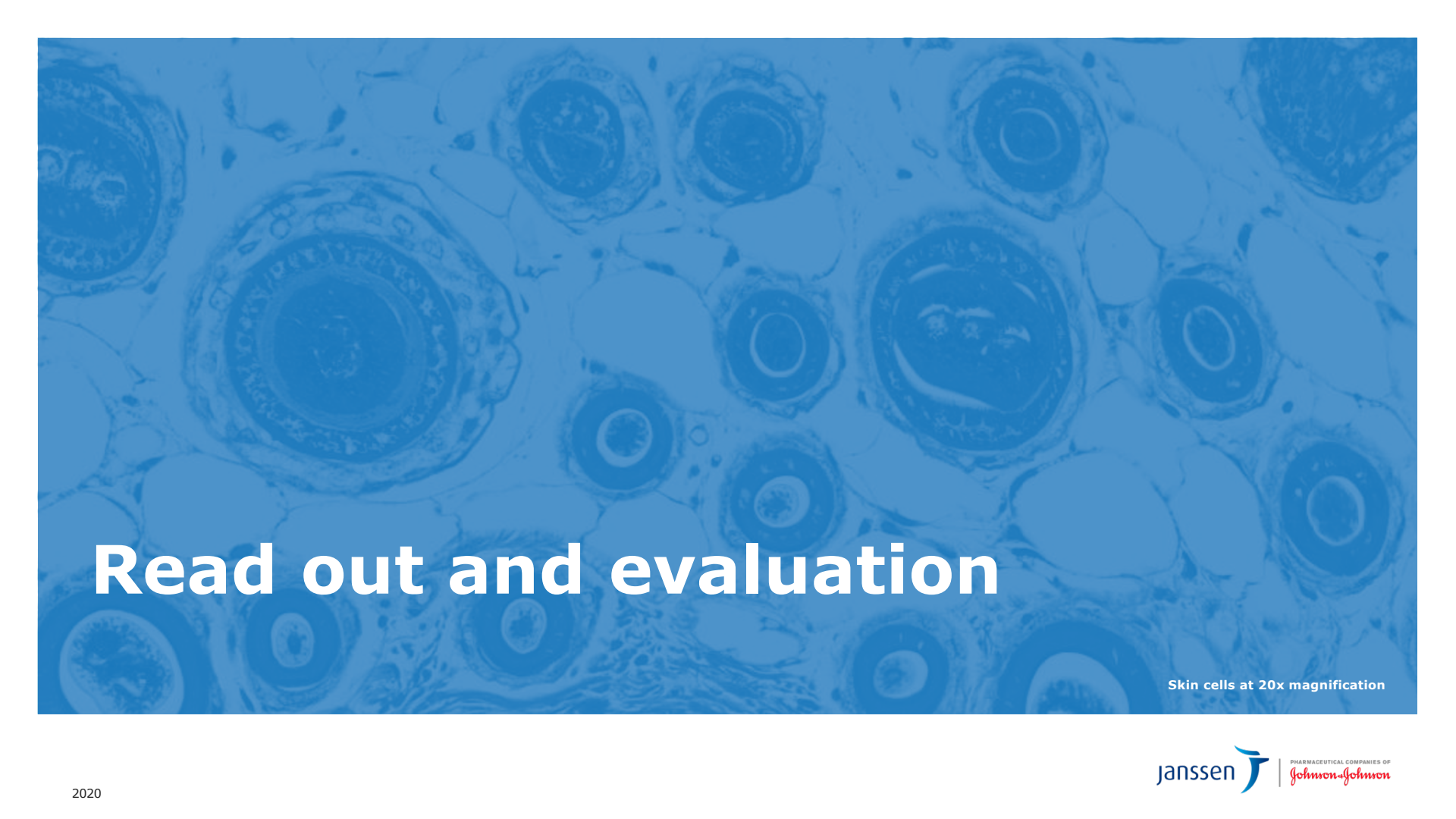
CRF Version 17176 - Page Generated: 13 Mar 2020 13:31:59 Romance Standard Time

Save

2. Adding additional visit days and assessments

```
////////////////////////////////////  
// Assessment form OID's (data request = ASSESSMENTS)  
////////////////////////////////////  
  
ArrayList assessmentFormOIDList = new ArrayList(new string[] { "X_NEURO_01", "X_FRESHBIOF", "DEA_ONC_001", "X_PSA", "VS_GL_900_UN",  
"LB_GL_903", "LB_GL_903_01", "LB_GL_905" } );  
#endregion CF_FX_PopulateAssessmentForm  
  
#region CF_FX_ADD_PAGENUMB_DSL  
////////////////////////////////////  
// Suffix for max page allowed (data request = PAGENUMB)  
////////////////////////////////////  
int pageNumb = 10;  
#endregion CF_FX_ADD_PAGENUMB_DSL
```

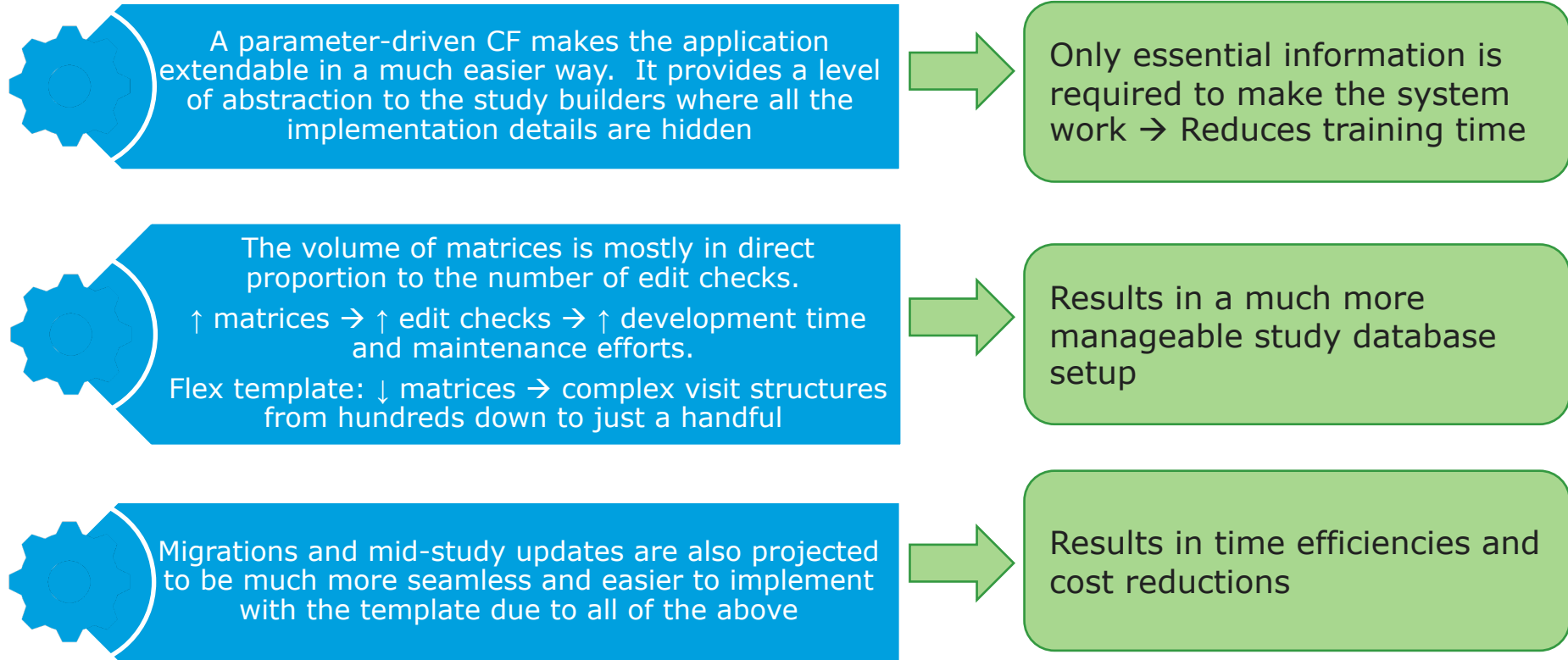
Forms that can be added via assessments form are listed in the custom function and easy amendable in a publish check migration



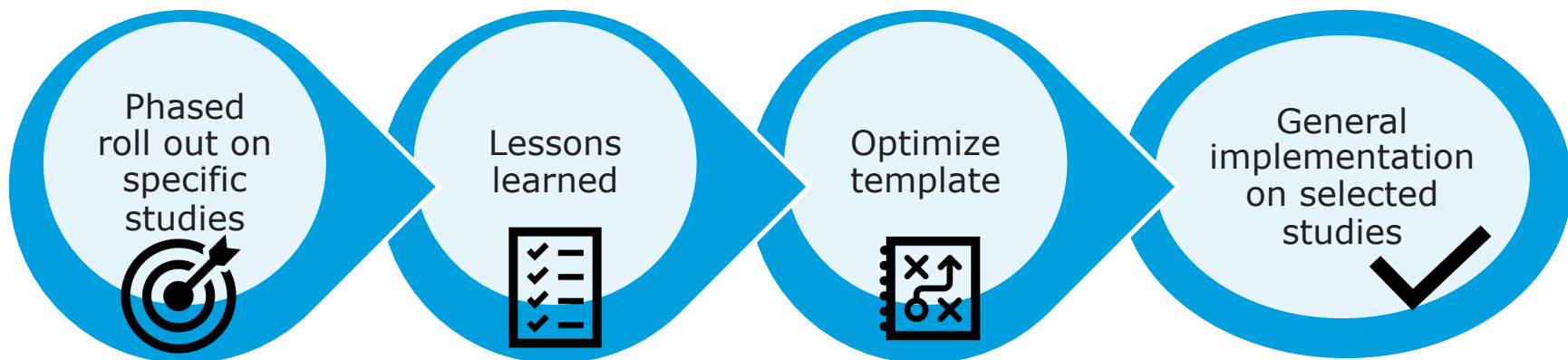
Read out and evaluation

Skin cells at 20x magnification

Template read out



Roll out of the template



Summary

The flexible template allows for

Easy and
standardized
implementation of
eCRF dynamics

Straightforward mid
study updates to the
eCRF Design

Flexibility on visit
schedule and
assessments
triggering



Team acknowledgement

Skin cells at 20x magnification

Oncology flexible template team

Central Services – Technical Data Architect

- Nele Claes (nclaes2@its.jnj.com)
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- Luca Guarnaccia (lguarna2@ITS.JNJ.com)
- Grégory Navarro (gnavar13@ITS.JNJ.com)

A photograph of a man with glasses and a young girl with long dark hair, both smiling and hugging each other outdoors. The man is in the foreground, and the girl is behind him, resting her head on his shoulder. A blue horizontal bar is overlaid across the middle of the image.

Thank you!

Questions?



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