

Fully paperless or less paper? A journey towards the paperless lab

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EBF Technologies

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Nonclinical and Clinical Assay Sciences (NCAS)

- Regulated bioanalysis, immunogenicity and biomarkers in nonclinical and clinical studies
- 90 employees (approx. half scientists – half lab techs)



Yesterday

- **Manual** documentation of
 - User
 - Date/time
 - Used stock batches & instruments
- **Manual** data collection for
 - Reporting
 - Data investigation



Challenges of paper-based lab processes

- Finding & gathering information
- Validating information & data
- Information & data availability
- Storage & archiving space

Solution

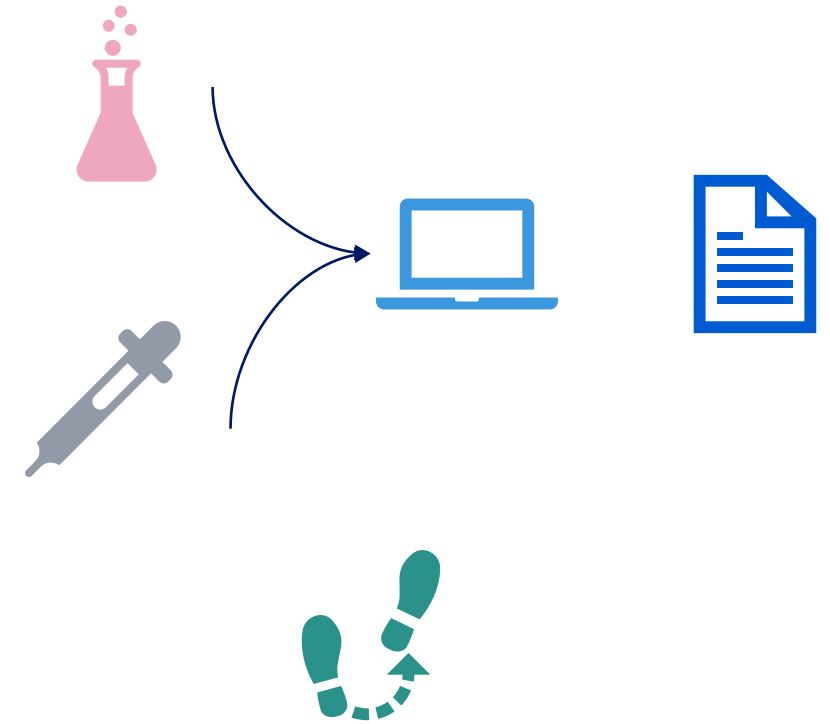
A laboratory information management system that

- manages **stocks** (reagents, antibodies, cells, etc.)
- manages **laboratory equipment**

to maintain **full traceability** from stock receipt to reporting.

Laboratory execution must **guide** users through lab processes and **document** used stocks and equipment.

Data available for **reporting**.



SampleManager

- Manages stocks and equipment
- Process execution capabilities
- Compliant with GLP
- Uses barcoding for stocks and equipment for traceability
- Advanced reporting

Laboratory Execution System (LES)

- Direct user to follow specific steps and document on the way
- Can calculate
- Can validate data in certain ranges
- Instrument interfaces

Data Validation

Only allowed to use **non-expired** stock batches and **available** instruments

Continue Laboratory Execution 'NN1965 (NNC0268-0965) RIA Rat & dog serum - Playground (013)'

Task Details

Name: NN1965 (NNC0268-0965) RIA R
Method: NN1965 (NNC0268-0965) RI
Assigned To: All NN roles
Started: 14-jan-2020 10:29

Select Project - Study - Run(s)

Select the Project, Study and Run(s) you are working on.

You can select up to 15 runs below if needed. Only one Run is mandatory in order to continue.

Progress

Step Name	Status
Force review	Review
Select Project - S...	In Progress

Parameters

Description	Value
Select a project	NN9499
Select a study	300131
Select a run	1
Select a run	2
Select a run	3
Select a run	4
Select a run	
Select a run	
Select a run	
Select a run	
Select a run	
Select a run	

Numeric parameter with range of 1 and 999999

Stop Back Pause Continue

Continue Laboratory Execution 'S000490-NaFa 3 Buffer (1L) (043)'

Task Details

Name: S000490-NaFa 3 Buffer (1L) (043)
Method: S000490-NaFa 3 Buffer (1L)
Assigned To: All NN roles
Started: 14-jan-2020 10:26

Add Na2HPO4

Add Na2HPO4:
Use a balance to weigh 5.77 g Na2HPO4 of stock S000043.

Progress

Step Name	Status
Add Na2HPO4	In Progress

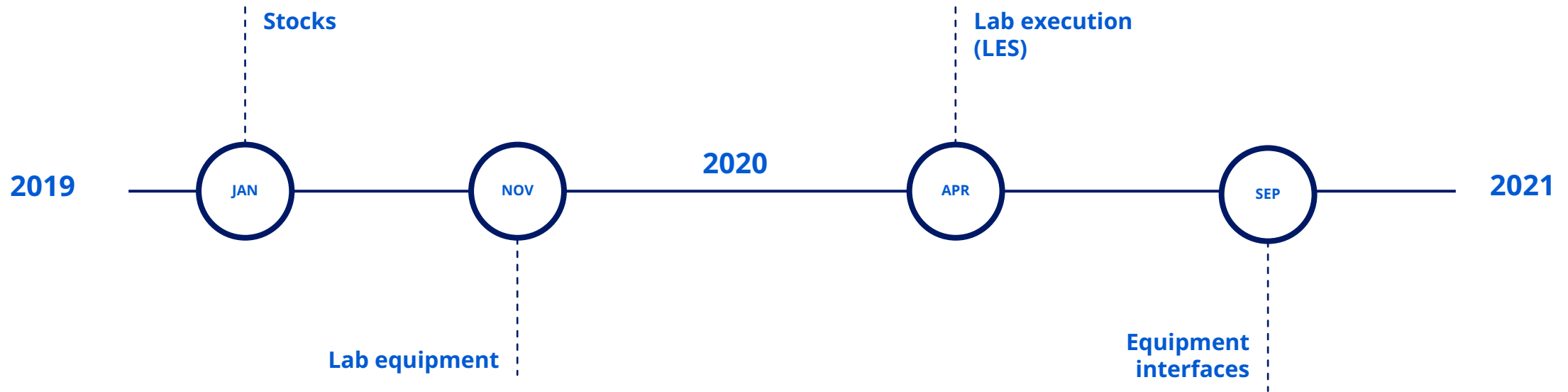
Parameters

Description	Value
Enter value for StockBatch	S000043/2
Enter value for Balance	In 0888
Enter weighed amount	5.77

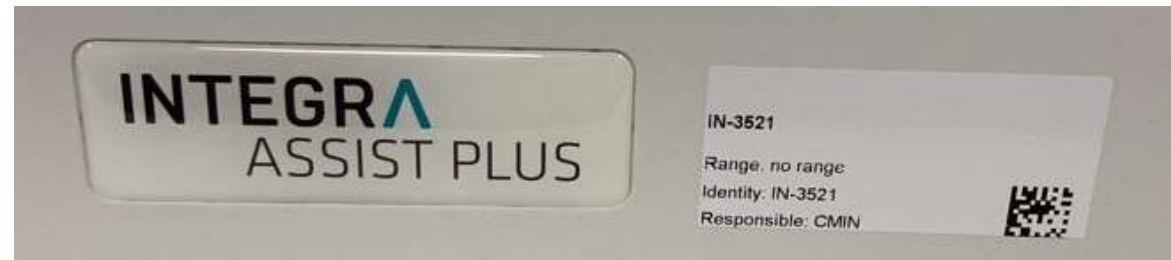
Numeric parameter with range of 5.76 and 5.78

Stop Back Pause Continue

4 Modules in Tiered Approach



Technical Setup



Technical Setup



A day in the (digital) life of a lab technician

1. Start SampleManager – personal login credentials
2. Start assay execution method
3. Follow directions in directions window
4. Document reagents & instruments where requested
5. Finalise execution
6. Hand off to study responsible scientist for review

A day in the (digital) life of a scientist

1. Review and approve a method execution
2. Once study is done, pull report

Calibrator					
Name	ID	Batch	Storage Condition	Expiry date	Supplier
Cal Rat	S001372/4	-	- 20 C	06-05-2021	Novo Nordisk

LCMS					
Name	ID	Batch	Storage Condition	Expiry date	Supplier
Acquity UPLC C8 BEH 2.1x50mm	S001076/6	01603030725115	RT	19-01-2031	Waters
Niflumic acid	S000990/1	BCBQ1458V PCode102069013	RT	26-11-2021	Sigma-Aldrich
Niflumic acid IS Predil	S001378/9	-	4 C	02-05-2021	Novo Nordisk
Analyte Stock	S001380/8	-	4 C	05-05-2021	Novo Nordisk
	S001380/9	-	4 C	05-05-2021	Novo Nordisk

LCMS Eluent					
Name	ID	Batch	Storage Condition	Expiry date	Supplier
ACN + 1%FA	S000237/17	-	RT	15-04-2021	Novo Nordisk
	S000237/18	-	RT	15-05-2021	Novo Nordisk

Reporting

Calibrator

Name	ID	Batch	Storage Condition	Expiry date	Supplier
██████████ Cal Rat	S001372/4	-	- 20 C	06-05-2021	Novo Nordisk

LCMS

Name	ID	Batch	Storage Condition	Expiry date	Supplier
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	S001380/9	-	4 C	05-05-2021	Novo Nordisk

LCMS Eluent

Name	ID	Batch	Storage Condition	Expiry date	Supplier
ACN + 1%FA	S000237/17	-	RT	15-04-2021	Novo Nordisk
	S000237/18	-	RT	15-05-2021	Novo Nordisk

Reference material

Name	ID	Batch	Content/ Concentration	Corr. for purity	Purity (%)	Bioactivity/ Potency	Storage Condition	Expiry Date	Supplier
██████████	S000961/2	██████████	-	-	81.56	-	- 20 C	28-05-2023	Novo Nordisk

Lessons Learned

- Implementation plan and OCM strategy
- Roll out in smaller phases to adjust along the way
- Monitor the system closely for data quality

Visions

- Robotic Process Automation (RPA) to develop the methods
- Scout other paper-based tasks to digitalise
- New release planned to include validation runs
- Automated reporting
- Investigate better technical solutions than laptops...
Tablets? Augmented Reality?



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