



## Pre-Advance Platform

*Sample Management and Processing by Mouse Click*

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DMPK / Bioanalytics



# Make the change



*"No, I don't want to change you, Darryl. But sure, it would be great if you were completely different."*

# Goals of preAdvance

**PreAdvance is a top down re-design of the PK sample management process** (Team lead by Novartis/DMPK Bioanalytics-CH)

- **Data Traceability on real time**
- **Increased automation of processes**
  - Data collection
  - Data handling and consolidation
  - Sample Management
  - Sample processing
- **Reliance of study data → increase in Quality**
- **Integration of data handling and sample logistics between Novartis and Central labs**
- **Reduced effort → increase productivity for all stakeholders**

# Issues can happen at any time



## Clinical site

- draws PK samples
- fills data in requisition forms



## Data programmer (at site)

- fills in eCRF
- populates clinical DB



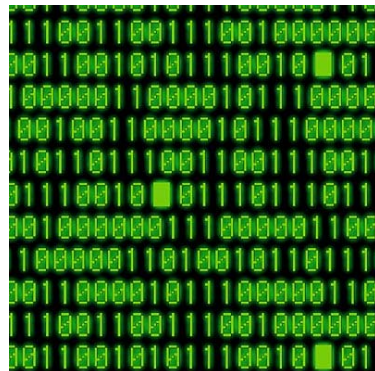
## Central lab

- Receives/stores/ships samples from/to sites around the world
- Generates manifests from eCRF information



## BA lab (internal or CRO)

- Enters samples in Watson LIMS DB
- Generates PK conc. data



## Data reconciliation

- Merges between Watson LIMS DB & clinical DB

# The Facts: Issues at the clinical site

- Storage/shipping conditions not followed according to the requirements
- Insufficient blood volumes collected
- Wrong matrices (e.g.: blood instead of plasma)
- Unscheduled time points



- Missing blood collection data in the clinical DB
  - BA received and analyzed “ghost” samples and generated PK concentrations
- Existing blood collection data in the clinical DB
  - No samples received at BA lab (Samples **lost** somewhere between clinical site and BA lab)

- Incorrect or unreadable patient ID written on tubes
  - Should be site#\_patient ID (e.g. – 1202\_00101)
- Wrong PK sample tubes used (e.g.- scheduled/unscheduled, wrong study)
- Wrong tube type used (biomarker instead of PK)

- Samples not checked by central lab
- Conflicting information on tube and manifest
- Insufficient information sent to BA lab (on manifest or on the tube)

samples with the same subject ID and sample number (but different accession numbers)



# Why is sample tracking so complex?

- Numerous manual steps
  - Data recording, sample labeling, generated duplicate/triplicate barcodes
- Late phase studies: Increase complexity of the process
  - Increase of clinical sites per study
  - Shift in focus to patient care vs science
  - Central labs supply the logistics for many diverse studies
    - customers, requirements, rules and procedures
- Lack of data integration across systems and services
  - Clinical database
  - Watson LIMS
  - Manifest file
  - CRO's

# Consequences

At the end the data reconciliation does not match!!  
→ BA people spend more time to track & identify samples than to analyze them!!



# How can we change that ?

Don't reinvent the wheel



Use existing technology



Standardization





# Key of the concept

Keep the first information from the very beginning to the end of the process

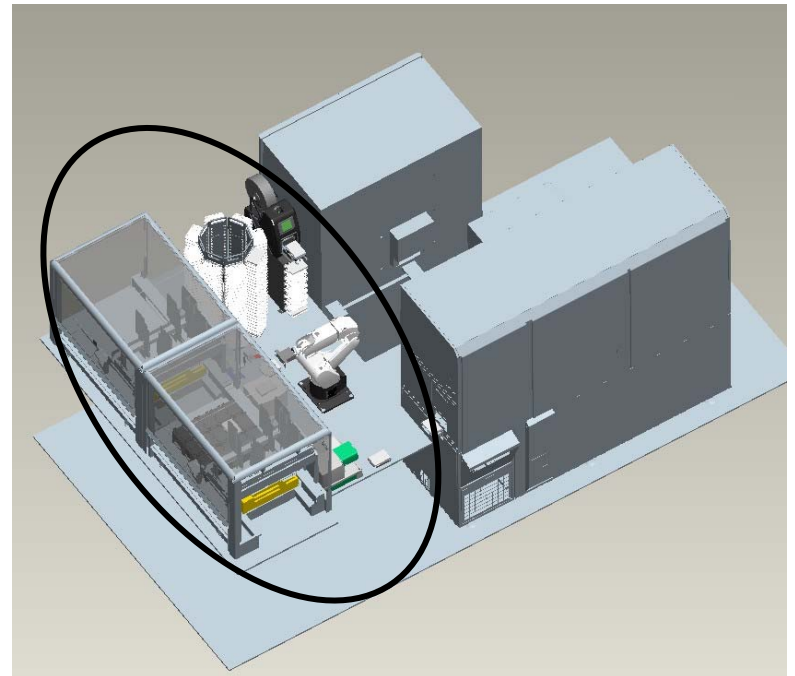
Data handling  
&  
Sample management



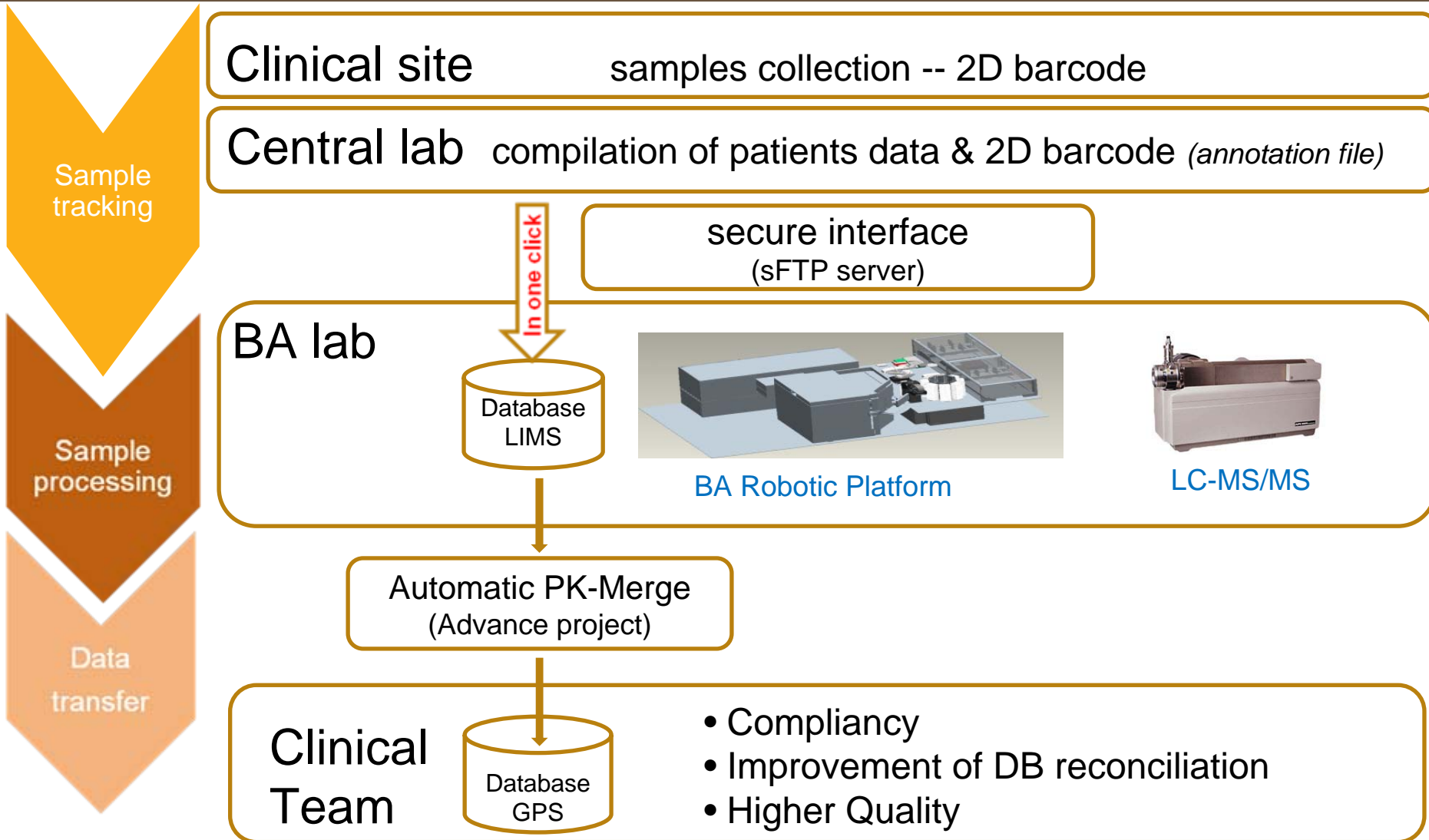
**The Key !!!**



Sample management  
&  
Sample processing



# PreAdvance concept: Overall workflow



## ....Enjoy the video...but few considerations

In the video, blood was substituted by red water to comply with safety policies during the video taping

The same plate has been used for the entire video and after multiple shakings for the shooting...it really suffered!!



# Video

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# Acknowledgments



X.Revet & M. Mekidiche-Laluc



C. Morel & A. Frittrang



J. Eich







Photo © Thomas Mayer

B. Brendani, M-Rose Fischer, M. Raccuglia, C. Emotte (Leader)  
O. Kretz (Unit head)

# Back up

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# References

Generic Name	Packaging Configuration	Tubes/case	Thermo Scientific Cat. n°	Description	Tube threads	Picture
Nunc 1,8 ml External Threaded 2D-coded tube 	48 tubes / rack	10 x 48 = 480	374500	NUNC External Thread 1,8 mL 2D-coded Screw Cap Tubes, Racked	External Thread	
	bulk-packed	480	374502	NUNC External Thread 1,8 mL 2D-coded Screw Cap Tubes, Bulk	External Thread	
	bulk-packed	480	374502NOV	NUNC External Thread 1,8 mL 2D-coded Screw Cap Tubes, with matching 1D barcode on side, Bulk-packed	External Thread	
	Latch-rack only	10 racks/case	331830	Nunc Latch racks, for 48 x 1,8 mL External threaded 2D-coded tubes	N/A	