

EBF

7th Open Meeting Beyond the Horizon - Painting a new landscape

A perspective on paperless operations in a
modern bioanalytical laboratory



Spotlight on e-Data Workshop
Jim Brennan
Wednesday 19 November 2014

Enterprise Laboratory Platform



Abstract

The goal of eliminating paper in the bioanalytical laboratory has existed for decades. Many approaches have been employed to achieve this. Laboratory information management systems (LIMS) have been used successfully to maintain bioanalytical data, assuring their accuracy and consistency over the life cycle from the sample tracking, instrument results processing and final result reporting steps. As regulatory requirements increased, ligand binding assays became more prevalent and additional bioanalytical data needed to be captured electronically LIMS evolved and electronic laboratory notebooks (ELN) came into the mix. Now we see the achievement of a paperless bioanalytical laboratory is possible. Added benefits of these efforts is a reduction in the data management burden on bioanalytical scientists, improved data quality review, more efficient reporting and cost savings for pharmaceutical companies and contract research organizations. This presentation will focus on the types of data managed by bioanalytical laboratories, common bioanalytical data management approaches, the supporting infrastructure and what is on the horizon for a paperless bioanalytical data environment.

Outline

- Going paperless in a bioanalytical laboratory
- Relevant e-data
- Commonly utilized software
- Approaches to eliminating paper
- Challenges with current approaches
- What's on the horizon and beyond

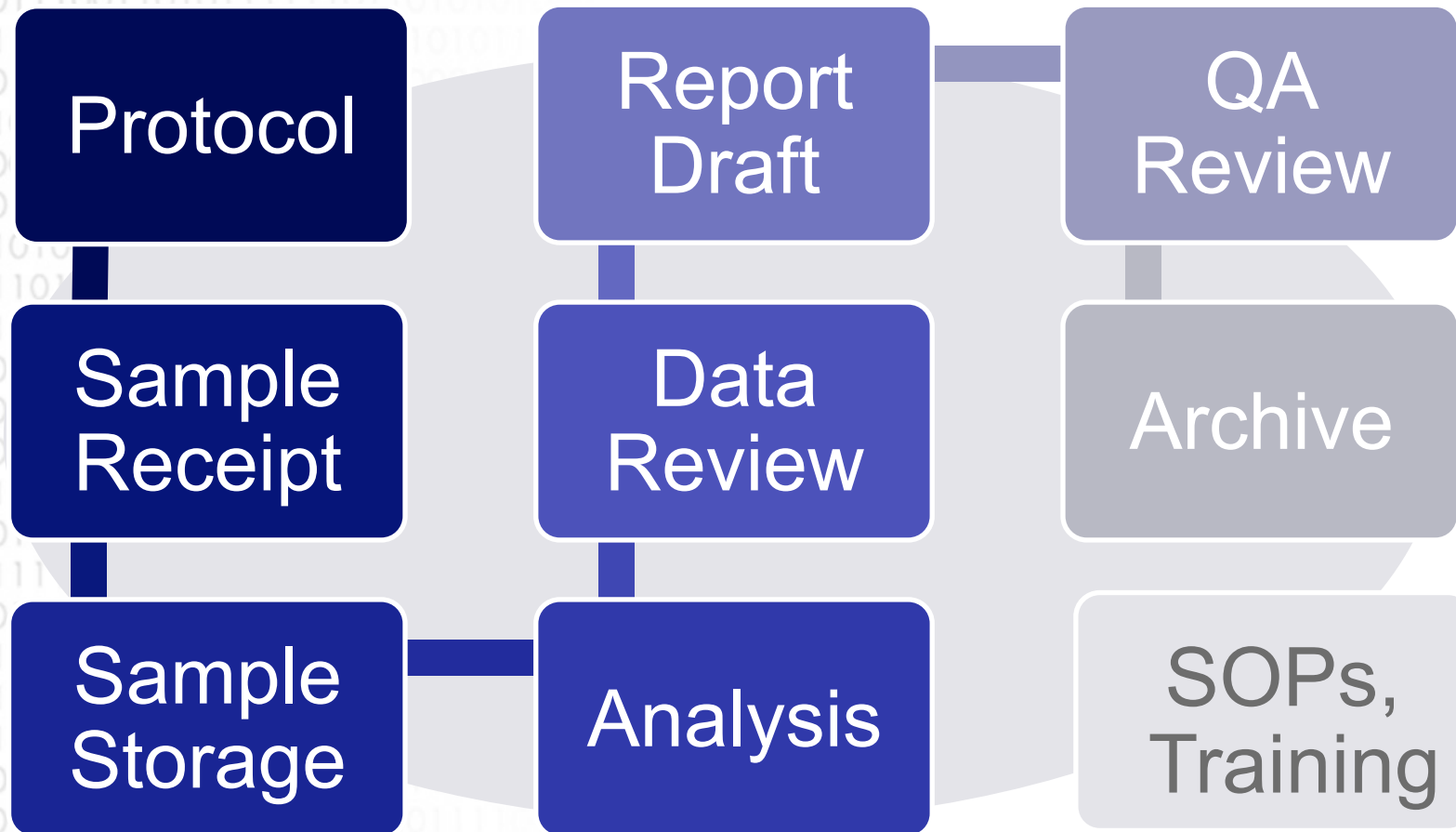
The Paperless Bioanalytical Laboratory

- It has been achieved!
- Scientists are managing data more efficiently.
- Data access has improved.
- Quality review is easier.
- Reporting is better.



Are these paperless systems fast, easy-to-use, interoperable, compliant and truly paperless?

e-Data in Bioanalytical Processes



Adapted from Patel, S., Huang, Q., Jian, W., Edom, R., and Weng, N., Overview: Fundamentals of a Bioanalytical Laboratory, 2013, in Li, W., Zhang, J., and Tse, F.L.S., Handbook of LC-MS Bioanalysis: Best Practices, Experimental Protocols, and Regulations, Wiley, Hoboken, p. 15.

Some Common Bioanalytical Software



Laboratory Information Management System

- Track samples
- Manage laboratory work
- Capture results
- Produce laboratory reports



Electronic Laboratory Notebook

- Replace paper notebooks
- Document research
- Experiments & Procedures



**Scientific Data
Management System**



Data Acquisition System



**Document
Management System**

LIMS and ELN

LIMS:
Log Samples

Lab Workflow
Management

Review and
Report Results



ELN:
Procedures &
Methods



LIMS and ELN



But we have many coins in our pocket!

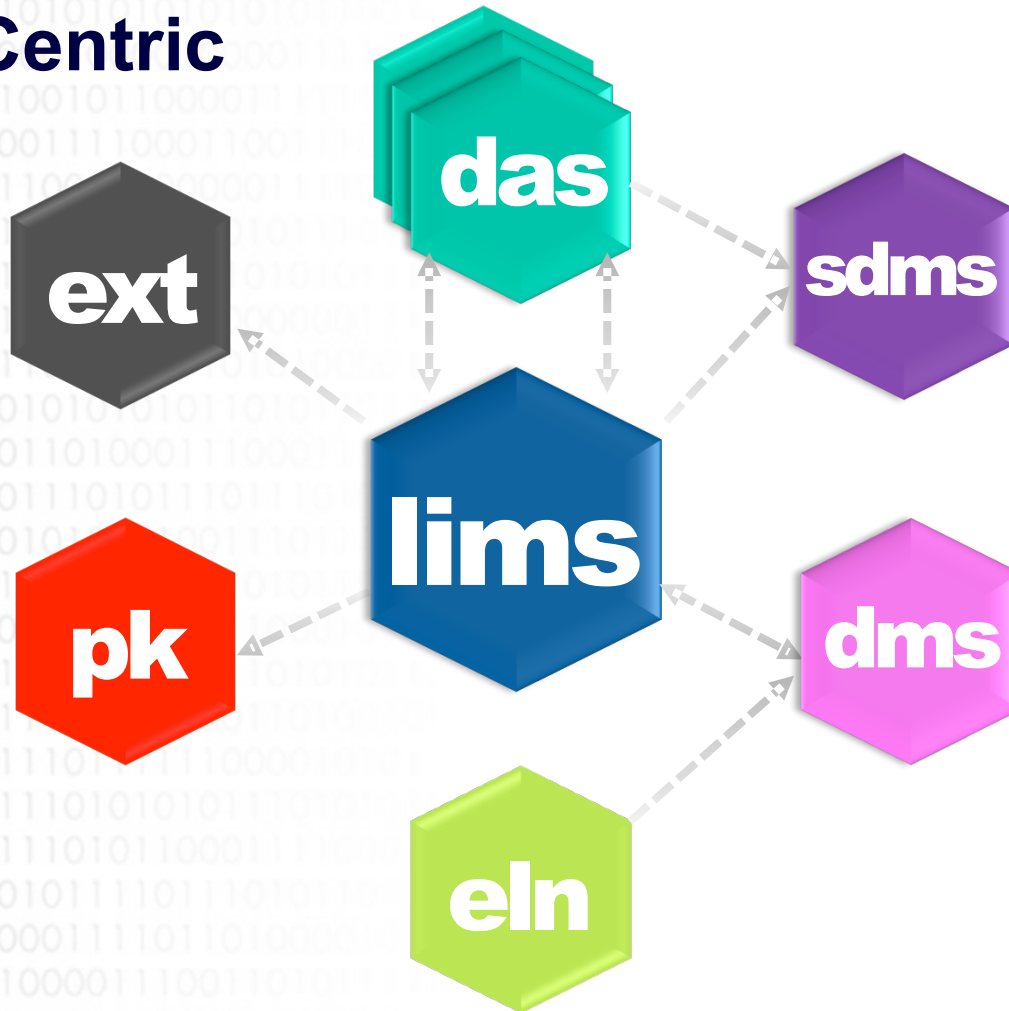
Bringing the pieces together

- **Efficient interoperability**
- **Tools to extract data from one system and export to others**
 - Files
 - Database to database
 - API
 - Web Services
- **Which data?**
- **Some examples...**



Bioanalytical Software Tools

LIMS Centric



Bioanalytical Software Tools

Report Centric



Bioanalytical Data Management Systems

Study Centric

lims

- SAMPLES
- TESTS
- RESULTS

report

- TABLES
- GRAPHS
- TEMPLATES

eln

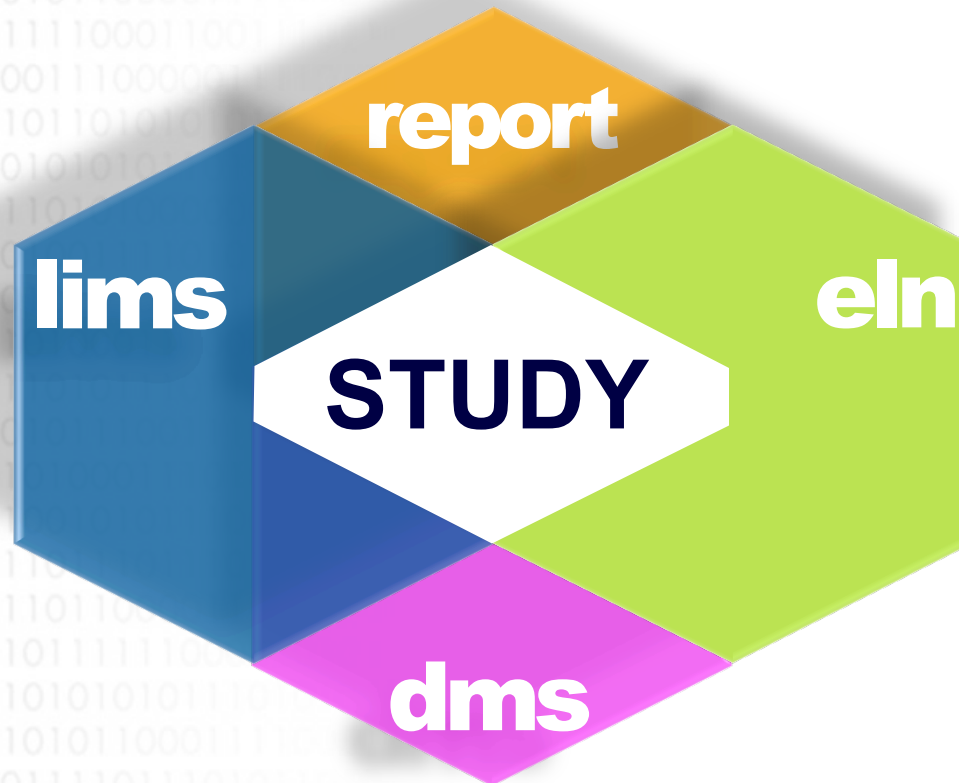
- EXPERIMENTS
- PROCEDURES
- LOGBOOKS

- REVIEW
- APPROVAL
- STORE REPORT

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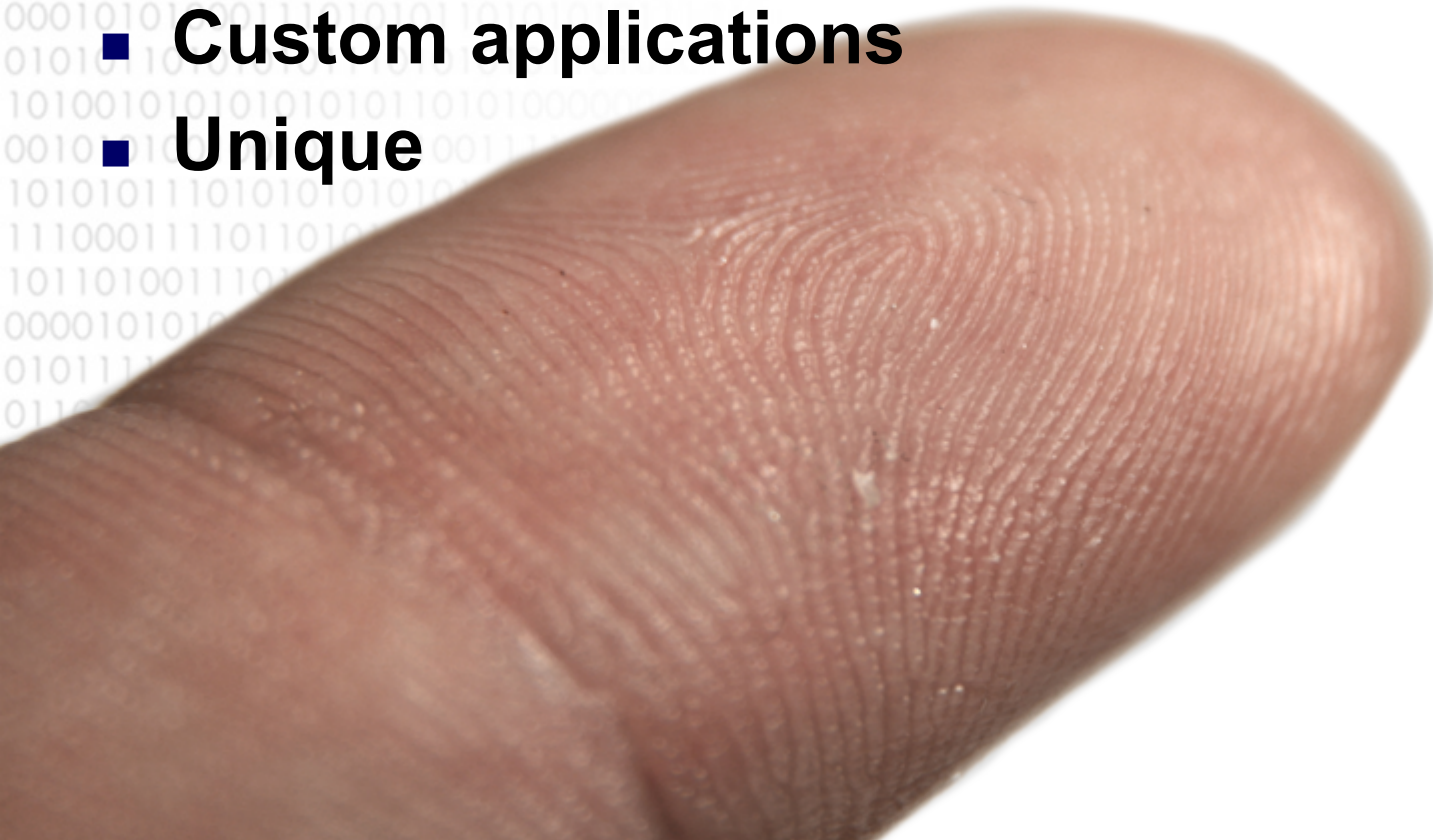
Bioanalytical Data Management Systems

Study Centric



Bioanalytical Data Management Systems

- **Diverse combinations**
- **Developed gradually**
- **Custom applications**
- **Unique**



Challenges

- **Maintaining multiple systems**
- **Interfaces**
- **User acceptance and training**
- **Validation**
- **Flexibility**



Bioanalytical Data Management Horizon

Rethinking Bioanalytical Data Management

- **Open-source software**
- **Common data standards**
- **Convergence of informatics systems**

Open-source software

- **Economical**
- **Built collaboratively**
- **We already see it in bioanalysis:**

6th Open Immunogenicity Congress Lisbon 2014
Cutpoint estimation assuming a mixing
distribution within the mixed model - using R

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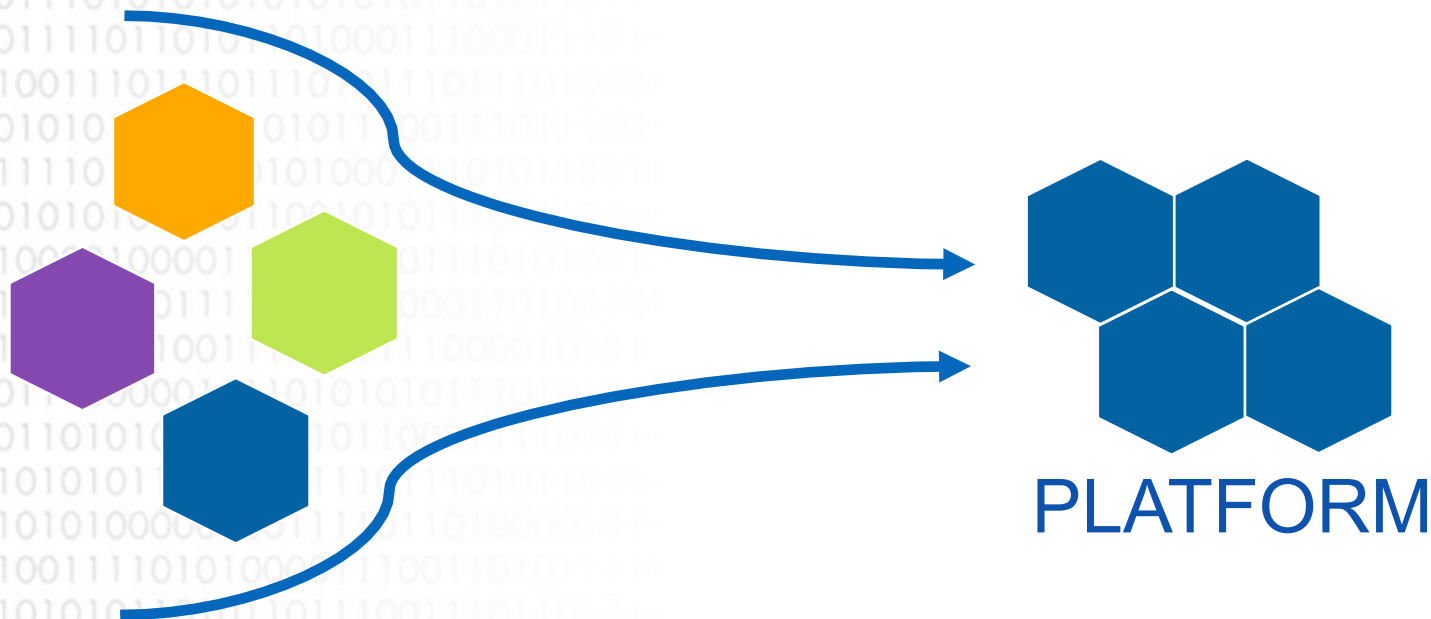
Common Data Standards

- More than just savings in time and money
- More than just interoperability
- Data accuracy
- Scientists can do the science
- Easier transfer of data between partners
- Decision making is simplified



Convergence of informatics systems

- **Complimentary functionality**
- **Evolving towards a common technology**
- **Less interfacing**
- **Still need interoperability**



Final thoughts on going paperless

- Many options for data management
- Watch for functionality overlap
- Plan well
- Ongoing support and maintenance
- Adaptability and flexibility

