



HEALTH SCIENCES  
**RECORDS & ARCHIVES**  
ASSOCIATION

# **Bourbon. Lampposts. And a Sense of Understanding**

## Perspectives on the Meaning, Value, and Integrity of Information

Russell Joyce, HSRAA Conference Manager & Publications Editor  
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# Disclaimer

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# Health Sciences Records & Archives Association

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- A non-profit organisation, established in 1981, aiming to exchange knowledge relating to the disciplines of records management and archiving with application in the life sciences, but also applicable in other regulated industries.
- Members include archivists, record managers and related roles from many leading scientific organisations, healthcare organisations, and commercial service providers.
- Current membership fee: £60 annually
- Further information:
  - <http://the-hsraa.org>

# Health Sciences Records & Archives Association

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- Promotes training in records management and archiving-related processes
- Advances the professional competency of its members
- Promotes co-operative relations with allied organisations
- Promotes standards of the profession of Archivists and Record Managers
- Publishes relevant information on the activities of the group and subject matters
- Organise meetings, congresses and symposia that allow exchange of relevant information

# Presenter –Russell Joyce

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- Independent Freelance Information Governance Consultant
  - 25+ years experience in life sciences, NHS, legal sector, professional services
- Executive Committee Member of HSRAA
  - (Co-) Author of numerous HSRAA publications including: eTMF Evaluation and Selection | TMF Relevant Communications Guidance | Guidance on the Scanning and Destruction of Original TMF Documents | Impact of EU536/2014 on Clinical Records Management | Evaluation and Selection of Commercial Archive Contractors | Guide to the Use of Digital Signature Technologies
- Co-Chair DIA Document & Records Management Community
- Member of DIA TMF Reference Model Steering Committee
  - Project Lead for Non-Interventional Studies TMF Definition Working Party
- Passionate tuba player



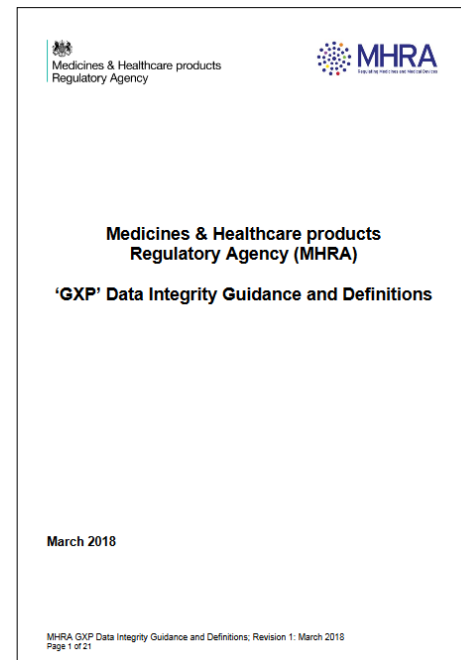


# Regulatory Frameworks & Guidance

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-  MHRA Guidance on Medical Device Stand-Alone Software (Rev. 2018)
-  EU Regulation 2017 / 745 Medical Devices (April 2017)
-  MEDDEV 2.1 / 6 Guidelines on the Classification of Standalone Software used in Healthcare within the Regulatory Framework of Medical Devices (2016)
-  IMDRF Software as a Medical Device Clinical Evaluation (2017)
-  FDA 21 CFR Parts 807, 812, and 814 Human Subject Protection; Acceptance of Data From Clinical Investigations for Medical Devices (2018)
-  FDA Use of Electronic Records and Electronic Signatures in Clinical Investigations under 21 CFR Part 11 – Questions and Answers (2017)
-  Selection of and Evidentiary Considerations for Wearable Devices and their Measurements for Use in Regulatory Decision Making: Recommendations from the Critical Path Institute ePRO

**FDA** **U.S. FOOD & DRUG**  
**ADMINISTRATION**



# Definitions

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- Software [MEDDEV]
  - “...a set of instructions that processes input data and creates output data”.
- Raw Data / Source Data [MHRA]
  - “...the original record (data) [...] the first capture of information [...]. Information that is originally **captured in a dynamic state should remain available in that state**”.
- Data Governance [MHRA]
  - “...data **ownership** and **accountability** throughout the lifecycle [...] the **design, operation** and **monitoring of processes / systems** to comply with the principles of data integrity”.
- Data Integrity [MHRA]
  - The extent to which “data is **complete, consistent, enduring** and **available** throughout the data lifecycle”



# Data Integrity -Principles

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- **A** Attributable
- **L** Legible
- **C** Contemporaneous
- **O** Original
- **A** Accurate
  - + Available, Complete, Consistent, Enduring
  - + Credible, Corroborated



[Metadata](#)

# Data Integrity -Landscape



## Technology

- Enabling technologies
- Wearable Device, Applications, Sensors, eDC



## Policies

- Legislation, Regulations, Guidelines
- SOPs, Procedures, Work Instructions, Manuals



## People

- Contributors, Users, Consumers



## Training

- Tutorials, Workshops

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Traceability  
Provability  
Integrity  
Meaning  
Context  
Knowledge  
Quality

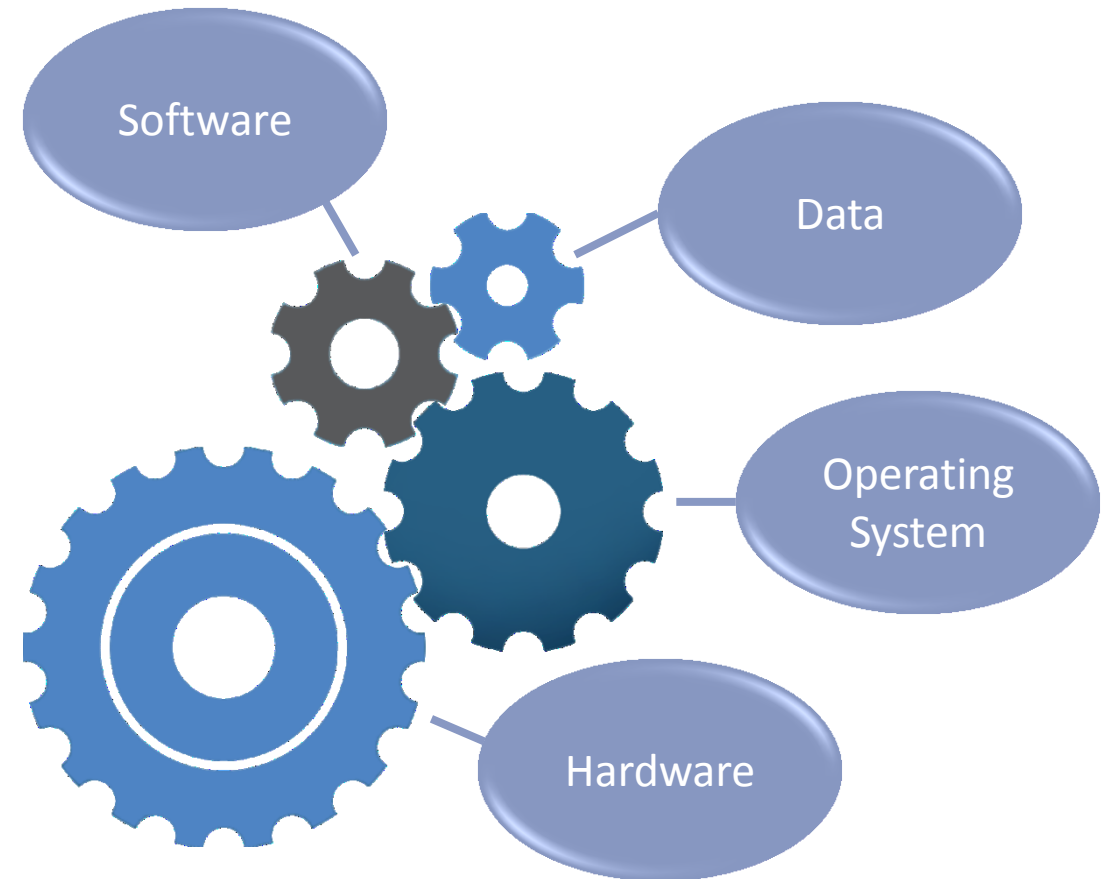
# Metadata Context

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# Technology -Interoperability

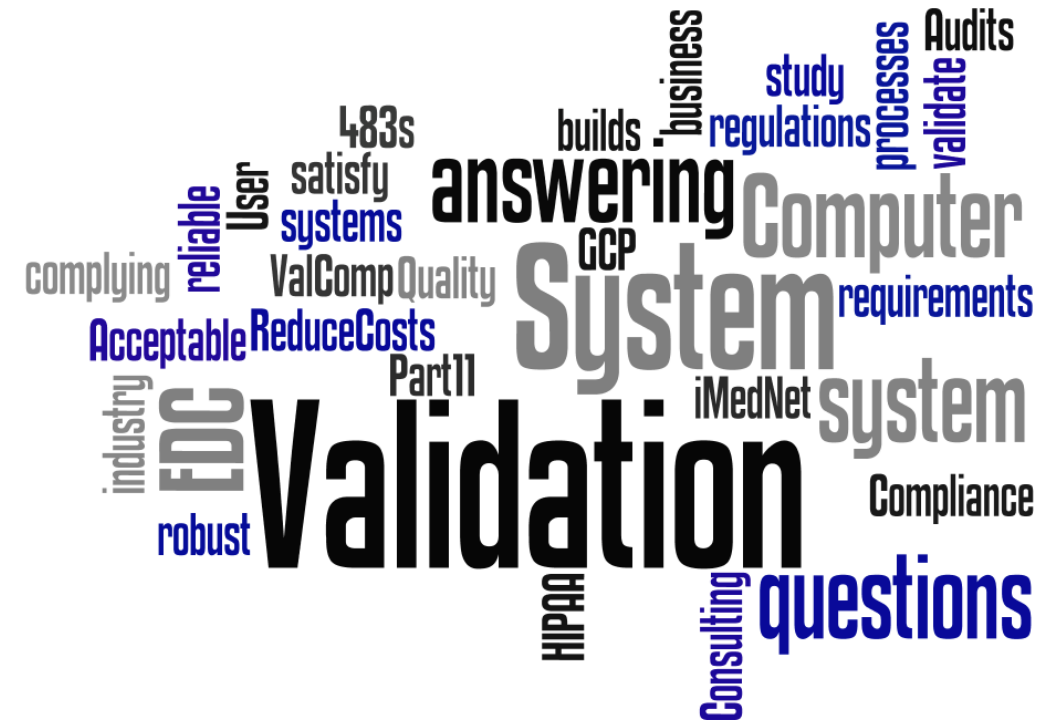
- Data
  - Format, Frequency, Volume
- Software components
  - Data collection, processing, applications
- Operating systems,
  - Processors, communications programmes, SoUP
- Hardware
  - Device, computers, servers, networks



# Technology -Equipment Qualification / Validation

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- Validate technology prior to purchase
  - Ensure “fitness for purpose”
  - Reliability of capture, transmission, and recording
  - Accuracy, reliability and completeness of records
  - Reliability of data entering sponsor’s EDC
  - Reliability after device and software updates
  - Measures what it is designed to measure
  - Ensure requirements for exit scenario
  - Define migration / conversion / preservation strategy



# Policies -Dealing with the Data Tsunami

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- Protocol development issues
- How to unlock the value of the data?
- More data does not translate into better data
- Value not in device but ability to extract raw data and leverage real-time analytics
- Define (among others)
  - Data originator identification
  - Access controls
  - Security and Confidentiality
  - Raw data / source data location
  - Transfer mechanism
  - Metadata / Audit trails
  - Data Manipulation
  - Data Analysis
  - Storage
  - Archiving





# People

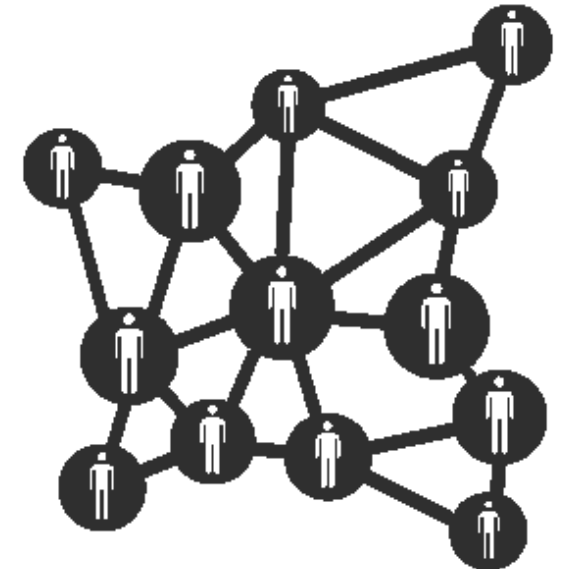
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## Internal

- Study Director
- Clinical Manager
- Data Managers
- Data Analysts
- Statisticians
- Quality Assurance
- GxP Archivist
- ICT
- Device / System Owner
- Procurement
- Project Manager
- Risk Management

## External

- Software Manufacturer /Supplier
- Device Manufacturer /Supplier
- Ethics Comr
- Investigator
- Regulator
- Patient
- Carer



# Training

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- Devices designed to present data to consumer
- Guidance on how to use on centralised database
- Understanding algorithms used in the device
- Wearing the device
- Following prompts
- General device familiarity
- Uniform handling
- Device functions
- Troubleshooting
- Device Manual
- Data Recording Instructions
- Data Upload / Download



# Bourbon? Lampposts?

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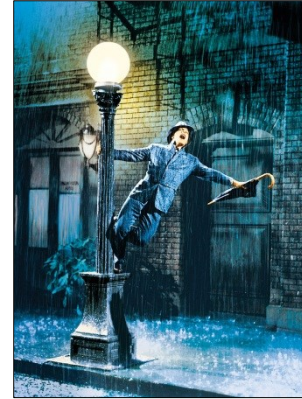
- “Gentlemen ...use manuscripts as drunkards use lamp-posts,—not to light them on their way but to dissimulate their instability.” (Alfred Housman 1903)
- “He uses statistics as a drunk uses a lamppost - for support rather than illumination” (Andrew Lang 1912)



# Twelve Uses for a Lamppost

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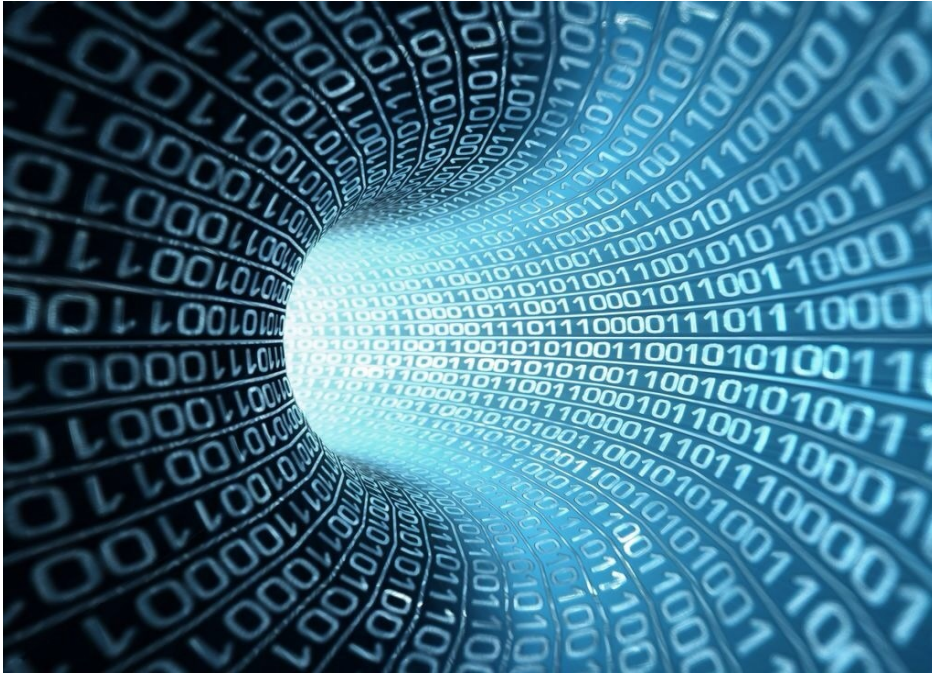
- |                 |                  |                        |
|-----------------|------------------|------------------------|
| 1. Illumination | 5. Anchor        | 9. Signage             |
| 2. Support      | 6. Measurement   | 10. Advertising        |
| 3. Direction    | 7. Resting Place | 11. Dance prop         |
| 4. Decoration   | 8. Home          | 12. Territorial Marker |





# In Summary

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- Know what you want to measure
  - Find a “fit for purpose” device
  - Validate and support the device
  - Ensure reliable transfer of accurate data
  - Plan for objective data analytics
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- Golden Rule: Understand the purpose, meaning and value of your data

# Questions

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