



FDA eSource Interpretation & Implementation from Technique Point of View

**PhUSE SDE-BJ
2017-05-19**

Because We Care



Ensuring the eSource's

- Reliability 可靠度
- Quality 品质
- Integrity 完整度
- Traceability 可追溯度



eRecord vs. eResource



Scope

- From electronic source
- To electronic regulatory submission





Let's again talk about the Laws



FDA's Position

- eSource Data in Clinical Investigations IG 2013
- ePRO IG Patient-Reported Outcome for Device Labeling 2007
- Computerized Systems used in Clinical Investigations IG 2007
- 21CFR Part11 – 2003
- Food and Drug Administration Modernization Act of 1997 (FDAMA) These changes were made in order to
 - Recognize the changes in the way the FDA would be operating in the 21st century.
 - Acknowledgment in the advancement of Technological, Trade, and Public health complexities.
- CPG#7150.13 – 1979~2004 allows *Risk Based Approach*
 - *Record keeping requirements*
 - *21 CFR 312.xx for Drug, Biologics & 21 CFR 812.xxx for Device*

Vital Signs

Blood pressure readings must be completed by an Omron device prior to 10:00 AM. The subject must have been seated for at least 5 minutes. There must be at least 2 minutes between each blood pressure measurement. Blood pressure and pulse rate will be determined and recorded in triplicate. The mean of these values will constitute the BP and pulse rate for the visit.

Arm Used: ☒ Left ☐ Right

Cuff Size Used: ☒ Regular ☐ Large

Blood Pressure #1: 110 / 00 / 160 / 98 mmHg

Blood Pressure #2: 110 / 05 / 120 / 75 mmHg

Blood Pressure #3: 110 / 10 / 120 / 75 mmHg

Mean Blood Pressure: 121 / 63 mmHg

Sitting Pulse Rate: 72 beats/min

Respiration Rate: 20 breaths/min

Temperature: 99.0 °C / 99.0 °F

Height: 75.0 in / 190.5 cm

Weight: 190.0 lbs / 86.4 kg

Body Mass Index: 23.9 kg/m²

Vitals Obtained By: [Signature]





eRecord vs. eSource



Source

- All information in **original** records and **certified copies of original records** of clinical findings, observations, or other activities in a clinical investigation used for reconstructing and evaluating the investigation
- **ALCOA**: Attributable(可歸屬的), Legible(易讀,明瞭的), Contemporaneous(同時發生的), **Original** & Accurate



eRecord

- Any combination of text, graphics, data, audio, pictorial, or other information represented in **digital form** that is created, modified, maintained, archived, retrieved, or distributed by a computer system 21 CFR 11.3 (b)(6)
- eCRF is an example





eSource

- Data **initially** recorded in electronic format
- Consisting of (sample next page)
 - Data Element
 - **Originator:**
 - Investigator and delegated staff (per DBP defined)
 - Subject/Patient and legal representatives (ePRO)
 - Automated lab reporting systems (Central Lab)
 - Consulting Services (MRI, CT, IVD reading/reporting)
 - eHR (Health Record)
 - Medical devices (ECG, BMI, HbA1c糖化血红蛋白)



The eSource: Data Element + Originator

 A bit interesting, aren't they?

Field in eCRF	Data Element	Data Element Identifier
Patient ID#	AD0012	Randomization algorithm in central computer/June 1 st , 2008/3.00 pm AD0012
Sex	male	*Investigator Dr R Smith/June 1 st , 2008/10.53 am AD0012
Age	25 years	*Investigator Dr R Smith/June 1 st , 2008/10.53 am AD0012
Hemoglobin	15.3 g/l	Co-op labs/June 2 nd , 2008/12:06 pm AD0012
Date blood was drawn for Hemoglobin determination	June 1 st , 2008	*Investigator Dr R Smith/June 1 st , 2008/10.53 am AD0012
Radiological report	"Right upper lobe consolidation"	Dr P Brown, radiological associates/ June 1 st , 2008/4.12 pm AD0012
Blood pressure	124/88	*AB instrument systems/ June 1 st , 2008/10.53 am AD0012
Concomitant medications	**Lasik 40mg QD	Investigator Dr R Smith/June 1 st , 2008/10.53 am AD0012

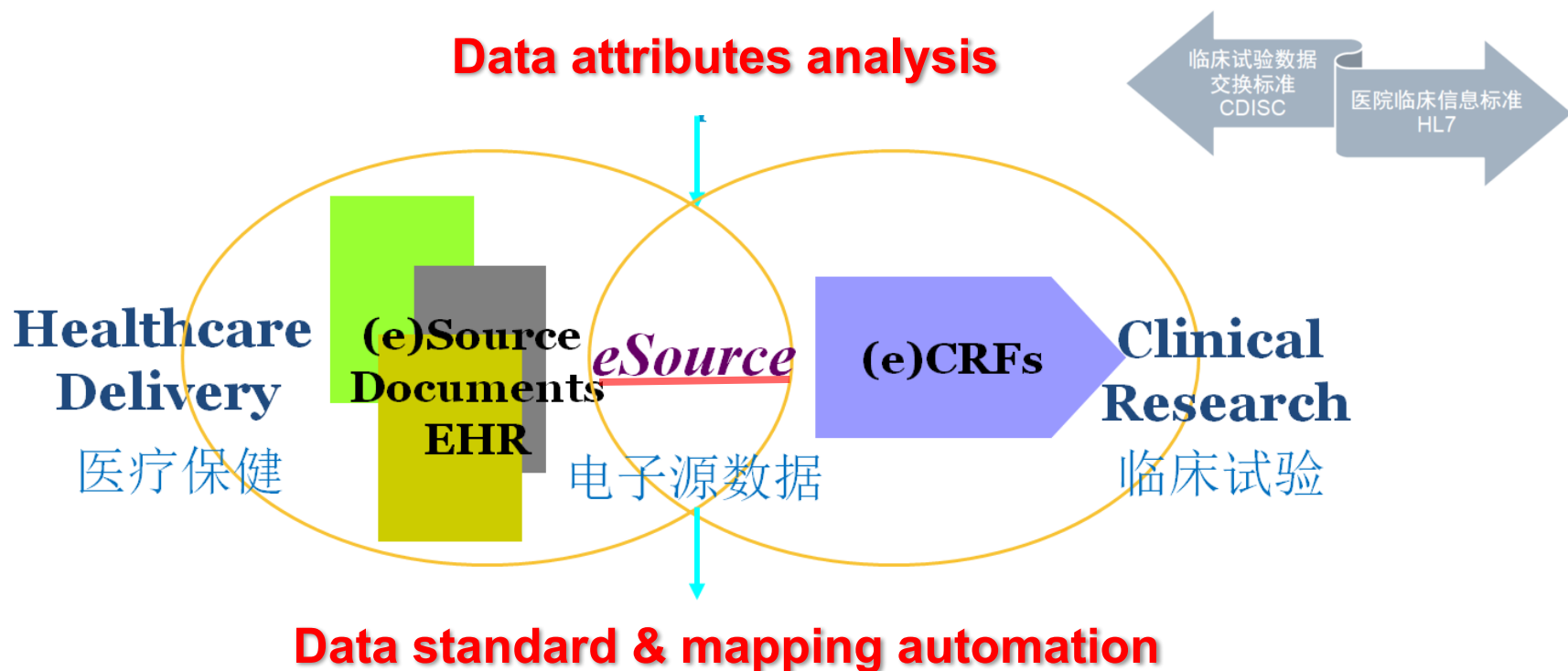




eHR = eSource ?

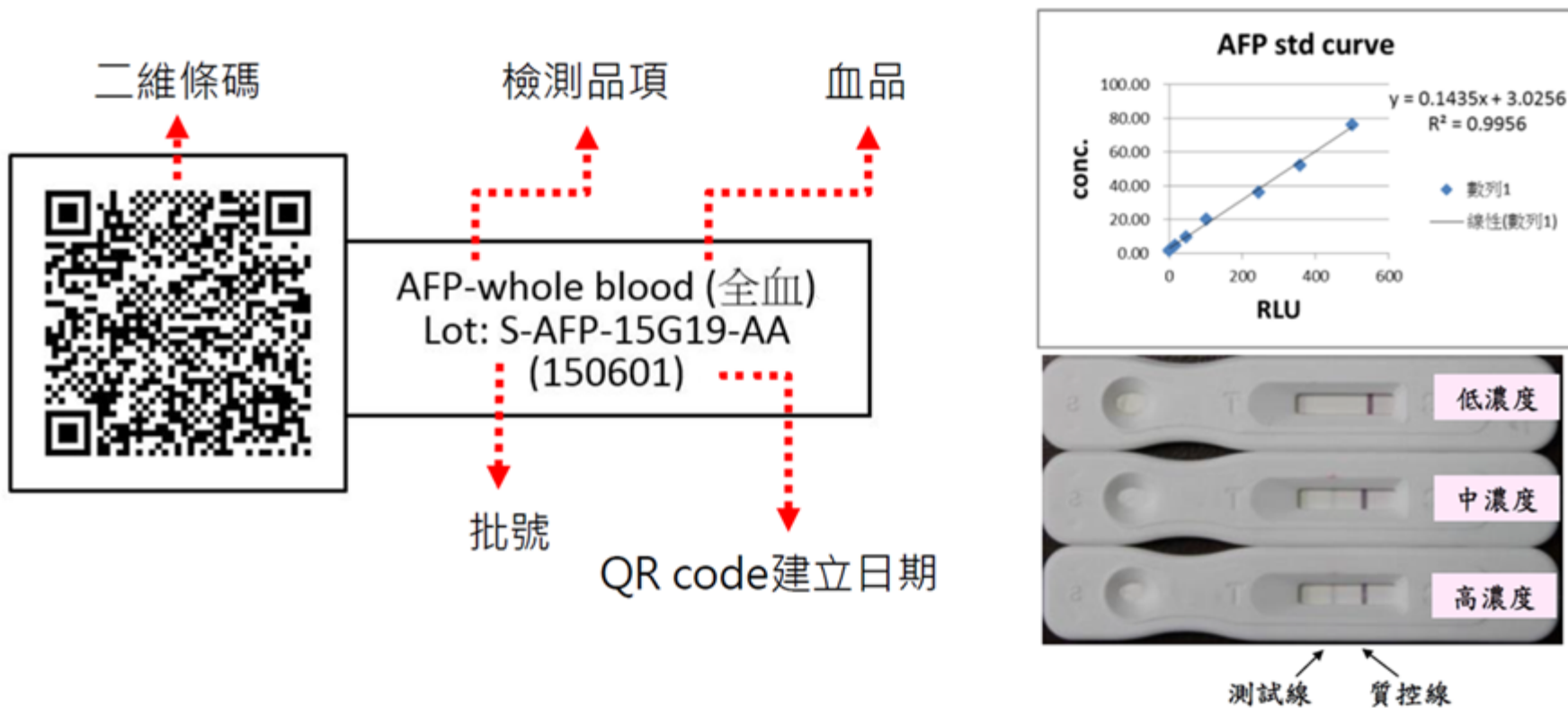
《中国临床试验数据标准化工作Q2研讨会》 2015年5月22日•上海•张江高科

- 主题：电子临床研究和电子医疗数据互联互通及电子源数据应用（临床试验数据流端到端系列研讨会之一）



Data Generation - ALCOA_{p5}

- Tons of material science R&D and clinical tests for reliable accuracy for Linear presentation and further feeding and analysis.



感谢 晶纬国际有限公司 张巍馨(Leeven)总经理提供上述材料



Data Experts are devoting to cross-brand Device Integration



SOLUTIONS

RESOURCES

NEWS AND EVENTS

ABOUT

SUPPORT

PERIOPERATIVE

ASC SOFTWARE SOLUTIONS

CLINICAL DOCUMENTATION

ANALYTICS

BILLING AND OPERATIONS

EMERGENCY

SUPPLY CHAIN

CRITICAL CARE

DASHBOARDS & ANALYTICS

MEDICAL DEVICE INTEGRATION

ASC DEMO

Comprehensive patient data,
when you need it, where you need it

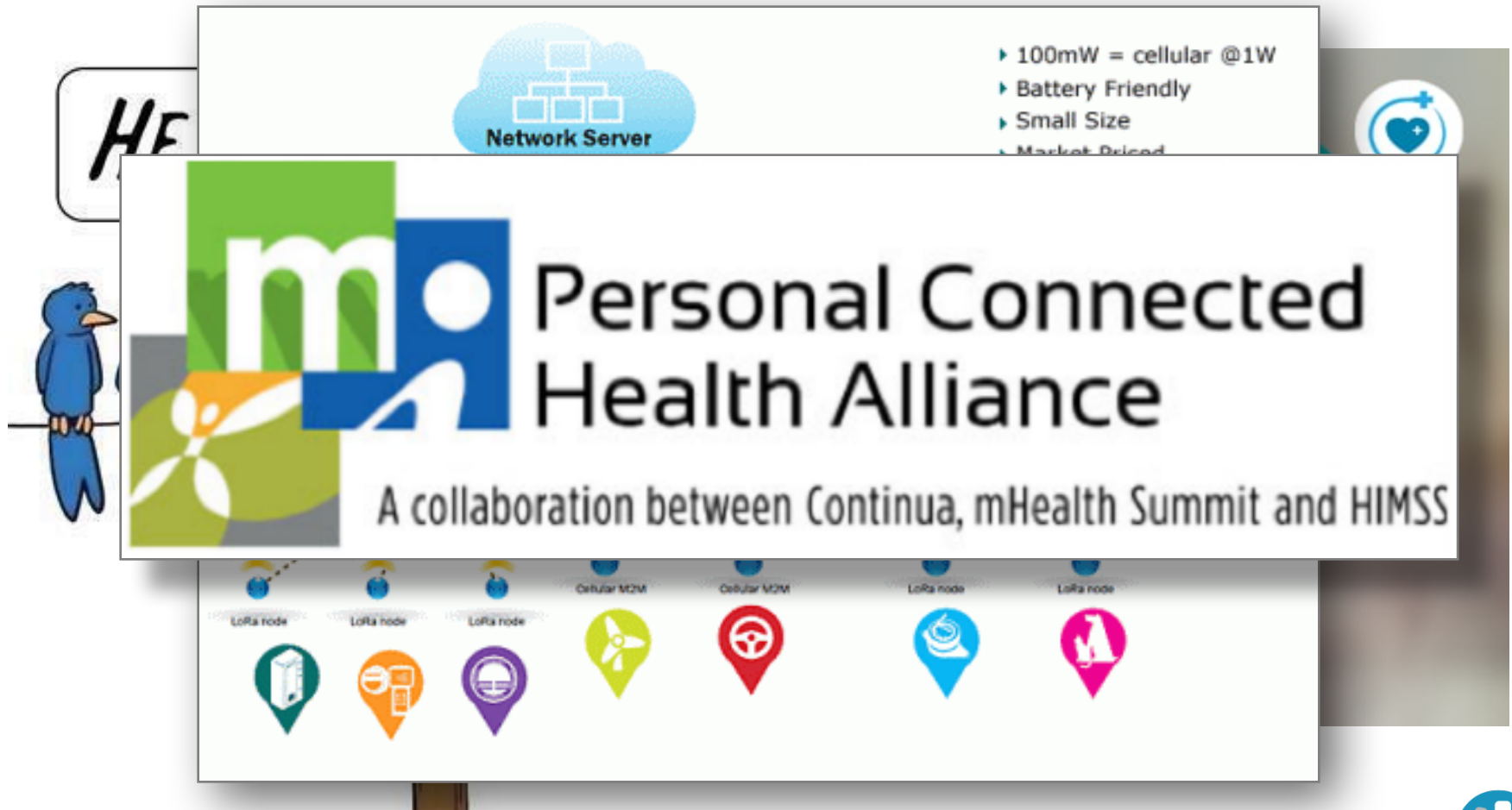




Journeys of the Data ~ Transmitting

Quality, Reliability, Safety, Privacy, Traceability

- ✚ IBM LoRa for Internet of Things
- ✚ Bluetooth for HL7





Cases to share – Non eCRF



ISO27001

Information Security Controls, by ISO 27001 Domain			
Question Number	Question/Request	Response	Additional Information
A4 - Risk assessment and treatment:			
Assessing security risks			
CISP1	Is a managed and maintained IT or Information Security Risk Management programme or policy utilized in your company and/or affiliates that has been approved by management and communicated to all employees, including subcontracted and outsourced personnel? If yes, and you have not provided any ISO27001 Certification, please refer to and complete the Orange section of the Documentation worksheet if not already completed.	Yes	MS Azure under CSP assures all server cluster under it have cascading certification of ISO27001
A5 - Security Policy:			
Information Security Policy			
CISP2	Is a managed and maintained Information Security programme or policy utilized in your company and/or affiliates that has been approved by management and communicated to all employees, including subcontracted and outsourced personnel? If yes, and you have not provided any ISO27001 Certification, please refer to and complete the Orange section of the Documentation worksheet if not already completed.	Yes	We take care our part but in this scope, MS may
CISP3	Are your company and/or affiliates policies regularly reviewed? If yes, state the frequency in the Additional Information column.	Yes	Every 6 month and per necessary basis



Wholeheartly believe Technology ??

- What Manufacturers may not explain
- 17% Medical accidents caused by the devices (14MAY17 SH)
- What mis-reading/transmitting may cause...



Always be alert on DATA





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