

IT Infrastructure, Informatics and Scientific Computing

IOM Forum on Regulatory Science

Sangtae Kim, Ph.D.

Executive Director

Morgridge Institute for Research

Madison, WI


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PUBLIC



Twin institutes under one roof on the UW-Madison campus

Opening Observations

- IT Infrastructure, Informatics and Scientific Computing

- Distinct but interdependent – define each term.
- Overlap in skill sets and people as one source of confusion.

Full disclosure: 15 years in scientific computing as UW-Madison Chem Eng professor; 6 years dealing with IT infrastructure as head of R&D IT in big pharma; and for the past 7 years academic research in “pharmaceutical informatics”.

- (Under)investment in *scientific computing* surfaced as concern in the IT subcommittee talks with FDA personnel. Today present IIRIS/COE as the cost effective approach to ramp up FDA capabilities in this vital area.
- Collectively, they form a “platform technology” for regulatory science.

Definitions

- IT Infrastructure

- Basic physical and organizational structures needed for the operation of an information system, e.g., data centers, networks, computer servers and storage systems and the organization of operations personnel.

- Informatics (Information Science)

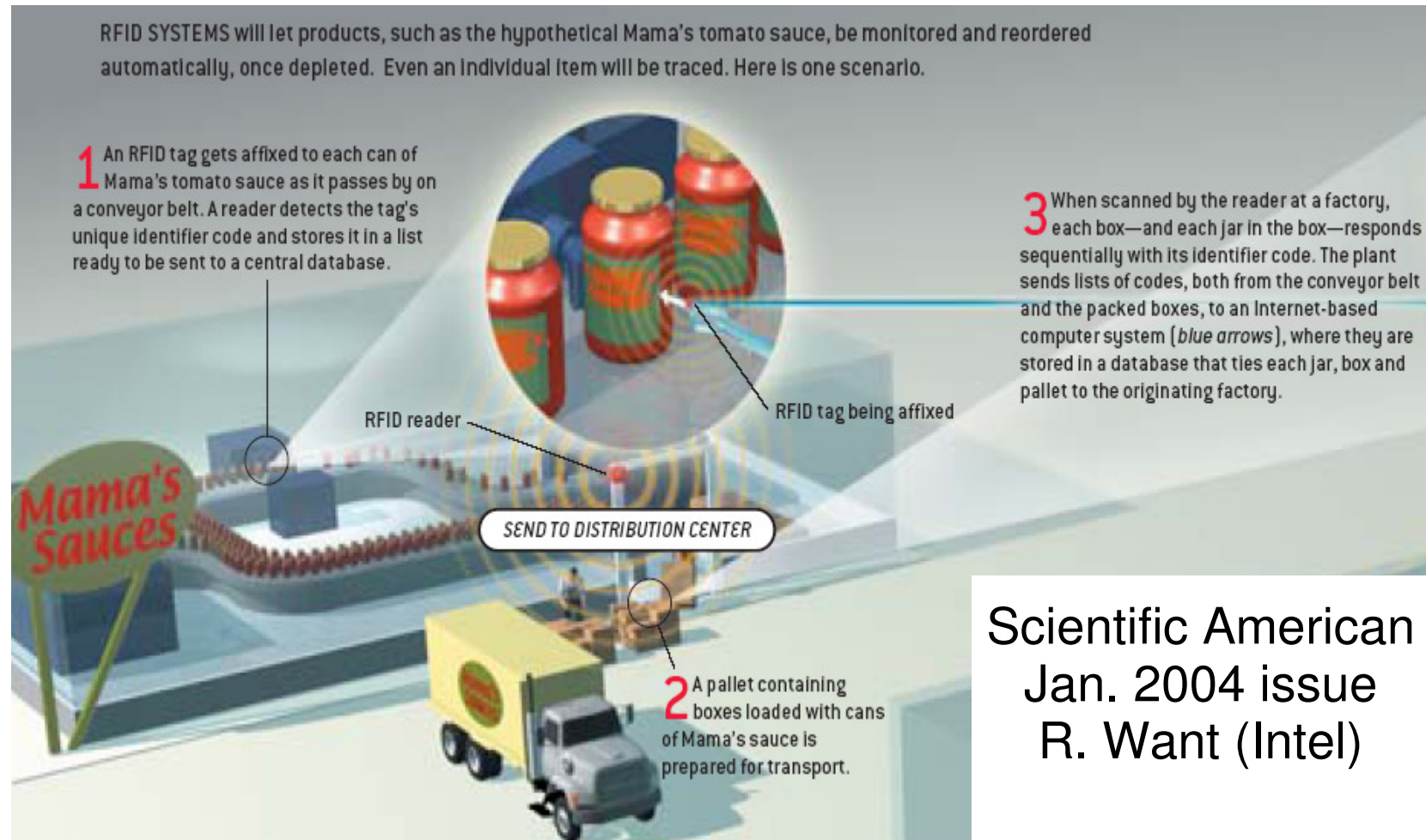
- The “science of information”, the practice of information processing, and the engineering of information systems ... studies the structure, algorithms, behavior and interactions of ... systems that store, process, access and communicate information.

- Scientific Computing

- Scientific computing ... constructing mathematical models and numerical solution techniques and using computers to solve scientific problems.

Increasing expectations of a data/IT-savvy public

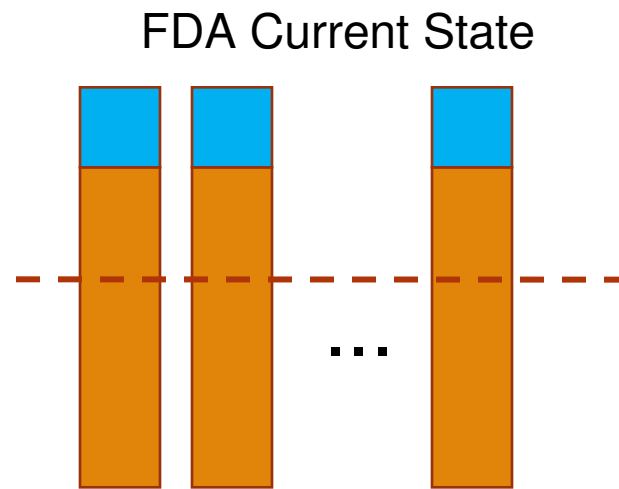
Example: RFID - the Electronic Bar Code and food safety



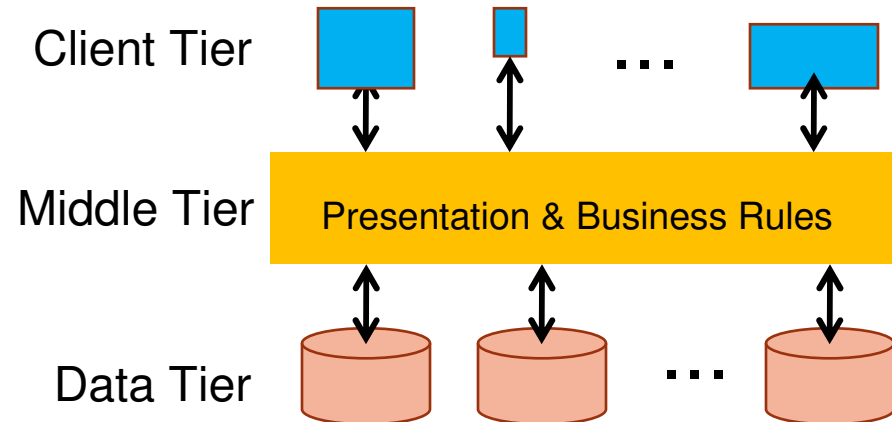
Scientific American
Jan. 2004 issue
R. Want (Intel)

Model of data sharing in IIRIS/COE

enabled by FDA strategy & vision for future state

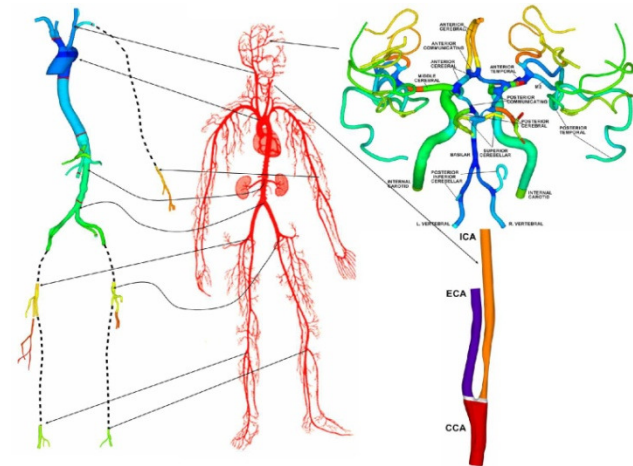
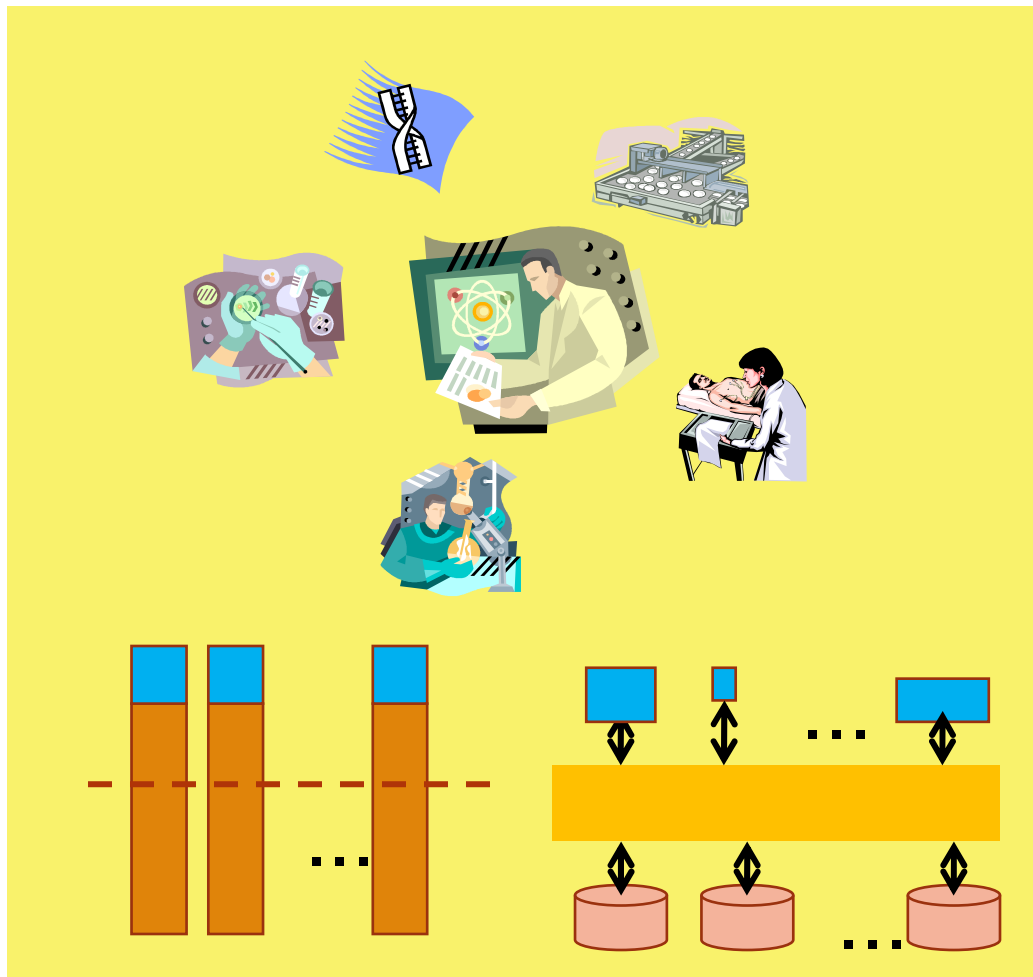


Migration is very expensive
(legacy of the past)



The Future State
Aligns with FDA strategy & vision
(migration would have been straightforward)

Leverage world-wide scientific computing



Glotzer report (2009) on
scientific computing: view
of world-wide activity
www.wtec.org/sbes

Conclusions and Discussion Points

- FDA IT Infrastructure
 - Major FDA investments underway – ICT21 – and with the transition from deficient to excellent IT infrastructure, the foundation is set for follow-on investments in informatics and scientific computing to leverage ICT21.
- Informatics
 - Rising expectations on safety issues from a data/informatics savvy public that is used to: social networking tech, tracking package shipments, new agile supply chains, ..., will place more pressure on FDA, if FDA is not set up for success in informatics & emerging tech combinations.

Conclusions and Discussion Points

- Scientific Computing
 - Scientific research no longer drives commodity computer-chip designs; creative response by world-wide network of scientists; increases relevance of the IIRIS-COE hub model for regulatory scientists to access functional scientific models and algorithms.
- Platform for IIRIS/COE Network
 - The “-omics” of emerging regulatory science challenges and opportunities depend on the triadic foundations of IT infrastructure, informatics and scientific computing.