US CASSS CMC Summary Strategy Forum: A Future Focused on Real-time Algorithmic Exchange and Processing of CMC data using FHIR

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Breakthroughs that change patients' lives

Paradigm Shift and Data Exchange Eras

- FHIR is causing a paradigm shift: Transition from Paper/ePaper era to Structured Data era
- "Accumulus will make interactions with regulators, data flow and the whole process of submission review and approval of assets a lot faster. Exactly how much faster we don't know today," Jeremy Chadwick, SVP and head global development office, R&D at Takeda Pharmaceutical Co. Ltd. (Tokyo:4502; NYSE:TAK) told BioCentury. He serves as chairman of Accumulus Synergy's board.¹ BioCentury Accumulus Synergy: modernizing interactions with and among regulators





Characteristics of each era

Era 1: Paper

- Time scale: Days
- High effort, Low volume
- Unstructured
- Sequential
- Monolithic

Era 2: Electronic Paper

- Time scale: Days, hours
- Lower effort, Higher volume
- Unstructured & semi-structured
- Parallel (Small scale)
- Monolithic

Era 3: Structured Data

- Time scale: Minutes, Seconds
- Lower effort, Very high volume
- Structured
- Parallel (Large scale)
- Granular



Comparison: Data exchange in the financial sector

High Frequency Trading

- Proprietary technology (Infrastructure and code)
- 🗴 Expensive
- 🏹 Structured data
- 🏹 High volume
- Ӿ Uneven playing field
- 🗴 Specific to finance

FedNow / Instant Payments

- Open source web standards (<u>ISO</u> <u>20022</u>, API, XML JSON, HTTPS)
- Free to use
- Structured data
- Fast (seconds)
- ✓ High volume
- ✓ Even playing field
- Specific to finance

Healthcare

- Open source web standards (<u>HL7</u> <u>FHIR</u>, API, XML JSON, HTTPS)
- Free to use
- Structured data
- Fast (seconds, milliseconds)
- ✓ High volume
- ✓ Even playing field
- Specific to health



FHIR Overview: Bringing the internet to health and biopharma

- Standard for encoding and exchanging health data in a machine readable and interoperable way.
- Free/ open source web standards used across sectors.
- Large community of developers and solution providers.
- Includes 151 pre-fabricated, ready to use templates (e.g., Medicinal Product, Organization, Ingredient).
- Multiple FHIR projects ongoing for biopharma use cases (E.g., labelling, CMC, AE, Clinical).





157 FHIR Resources (Prefabricated Templates)



157 FHIR Resources (Prefabricated Templates)





Data Exchange Industry – Pharmaceutical Quality (dx-PQ)



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Transitioning to the 3rd Era: Structured Data



Component Code: Description - Text: Desc Component



Taking FHIR's Resource approach to the next level





Business impact and considerations for the future

- Change management
- Data submissions (monolithic or granular data components)
- Increased submission bandwidth, throughput, frequency, and processing capability
- Innovation and creativity from real-time data exchange
- · System interoperability and data reuse
- The role of artificial intelligence



The biopharmaceutical industry has undergone previous transformation from paper-based submission to electronic paper submission. The industry is at the beginning of the next iteration of transformation, as signified by a transition to FHIR API data submission. This will be followed by further advancement as AI algorithms become increasingly prevalent. As the industry progresses in its journey towards digital maturity, faster submission and review processes will be made possible.

