White Paper

FHIR® for Life Sciences

September 2021

CitiusTech

INTRODUCTION

Interoperability in life sciences has always been a story of David and Goliath, putting pharma industry in an unprecedented situation where huge silos of data, which can be of meaningful use when interconnected. The business issues that life sciences need an answer to along interoperability are as follows:

- Need for a unified platform of interchangeable and operable data, for evidence-based insights.
- Trials to be more patient-centric for them to be an equal stakeholder in drug development.
- Need to integrate and manage laboratory and radiology information.
- Collaboration of data in real-time for meaningful insights and proactive signal detections.
- Connecting research scientist, their laboratories, and clinicians on a worldwide data platform for efficient preclinical development.
- Collaboration platform for data exchange with business partners and regulatory bodies.

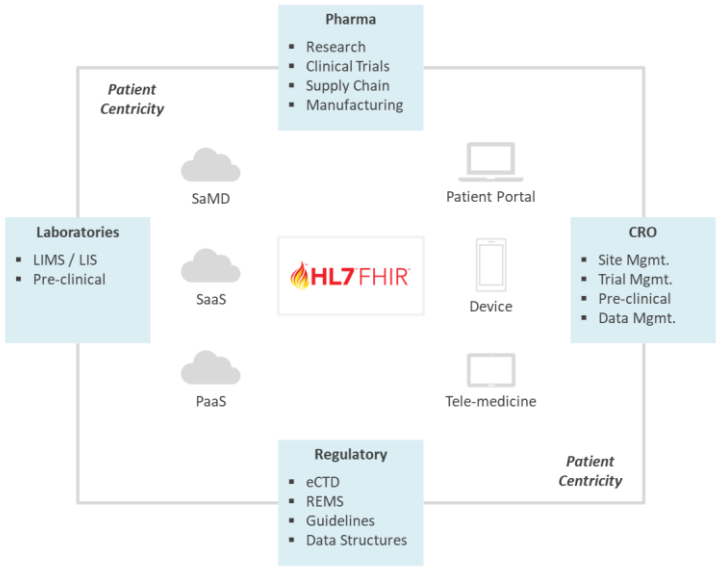

Fig. 1 – Model on Interoperable systems in Life Sciences

NEED FOR FHIR IN LIFESCIENCES

- Fast Healthcare Interoperability Resources or FHIR in short, an initiative to harmonize data exchange, is the answer to all the pain points mentioned earlier.
- EMR/EHR systems have patient clinical data stored in silos. This data is critical for conducting clinical trials as they form the core of efficacy and safety analysis.
- Significant amount of time is spent for manually entering data into the EDC systems and data entry errors often lead to more man hours for database cleaning.
- FHIR not only helps to create global resource libraries for data points in connected systems, but also enables the exchange of unstructured data.
- Handheld devices are increasingly becoming a medium for point-of-care and 'at home' data collection.
- Wearables and handheld devices capture large volumes of vital physiological information that are essential for critical endpoint analysis in clinical trials.
- FHIR helps organizations drive trials outcome for a real-world setting and allows clinicians to understand treatment pathways and disease progression.
- FHIR enhances collaboration between researchers, clinicians, and patients by collating unstructured data in Healthcare Clouds (HCC) platforms.
- It also drives advanced analytics of clinical data points in an informed manner.

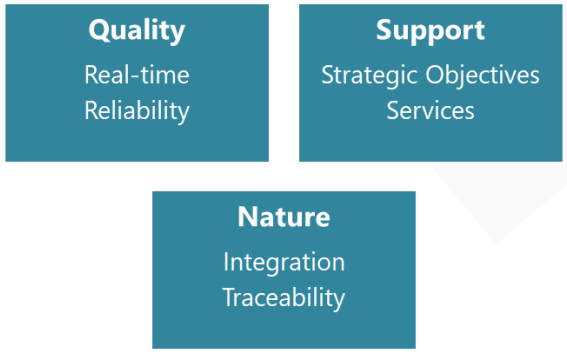

Fig. 2 – Key Objectives achieved by FHIR

FHIR: BENEFITS AND CHALLENGES

Benefits

1. One-time Implementation

FHIR is a one-time solution platform for seamless exchange of health data. Organizations can develop a SMART App on FHIR platform as per their data type and exchange requirement.

2. Patient Mediated Data

With Meaningful Use 3, SMART app, and the exchange flexibility of FHIR, members will have more access and control over their health data.

3. Easier Development

FHIR APIs such as RESTful APIs and OAuth2 provide a user-friendly experience to develop apps and exchange accelerators for FHIR.

4. Flexible Ecosystem

Most of the tech hubs of FHIR are public and not captive. This enables developers to create accelerators according to their specific needs.

5. Launch Apps in EHR

FHIR enables healthcare facilities to create and launch SMART Apps in the EHR environment. This enables data operators and owners to understand their data requirement, segregation, and exchange parameters.

6. Precise Interoperability

FHIR helps create data sub-units / discrete elements. This allows pharma / CROs to obtain specific data needed for EDC, CTMS, or eClinical Suite. Companies can keep their critical data and release data points that are necessary for process workflows.

7. Security

The exchange of data on FHIR can be classified into PHI, PPI, and CCI. Such information is intrinsic and confidential and needs a secure environment for data exchange. FHIR alleviates the concerns of the industry in terms of data confidentiality and data loss.

FHIR: BENEFITS AND CHALLENGES

Challenges

1. Version

For two systems to be interoperable, both should use common versions of FHIR.

2. Component Implementation

The systems that use FHIR need complete API implementation for seamless interoperability. Incomplete API implementation may result in inaccurate data exchange.

3. Data Point Matching

Creating and matching data resources within data systems is demanding. Constant vigil and testing is important, and compatibility can still be an issue due to its nascent stage. Changes made to patient information may result in inaccessibility for multiple systems.

FHIR: KEY DRIVERS AND AREAS OF IMPACT

- **Bring world closer**: As FHIR evolves, it will play a deeper role in the entire drug management cycle – from pre-clinical development to product portfolio management.
- **Patient Care Pathway:** Medical teams and product management teams will have real-time access to data available for portfolio management, supporting medical affairs department to understand the clinical decision pathway and map patient cohorts to the therapy profile of the drug.
- **Informed Medical Decisions**: Allow medical affairs, product management, and product strategy groups to gain insightful evidences into the treatment pathway and the clinical life cycle of the drug.
- **Synergize RWE:** FHIR aims to create data communities from data platforms, develop synergies between data platforms and organizations, enabling not only the researchers but also the marketers to gain insights regarding real-world evidence.
- **Data at Point of Care:** FHIR is bringing data to point of care, thus enabling clinicians not only to understand the real world assisted treatment pathway but also to make sound decisions.
- **Global Research Connectivity**: Interoperable and data exchange technologies such as FHIR will now help life sciences seamlessly connect all stakeholders – labs, pharmaceuticals, CROs, hospitals, regulatory bodies, academic institutions, government bodies, manufacturing plants, and supply chain.

Areas of Impact

Scenario #1 A pharma organization conducting a Phase 2 clinical trial on a rare disease needs to understand the therapy pathway and disease behavior. This will help gain access to the QOL (Quality of Life) of the patients in a real-world setting and help gain insights into the overall disease burden. Challenges include the following:

- Generating insightful data into the drug development pathway making informed decision
- Creating analytical outcomes and implementing changes to the trial conduct pathway and to the clinical/protocol-based decision-making process
- Obtaining real-time data from multiple hospitals and patients taking part in the clinical trial

The answer lies in FHIR and its capabilities in terms of SMART app.

FHIR: KEY DRIVERS AND AREAS OF IMPACT

Scenario #2 An international public health medical organization wants to study the epidemiological behavior of a pandemic, along with mapping the current treatment paradigm in different regions across the world. This will provide expedited and in-depth insights into patient care and management, disease behavior, drug development strategies, and public health and disease prevention strategies. The data resides across different EHR/EMR, LIMS, RIS, SAS, EDCs around the world.

The answer lies in FHIR and its capabilities in terms of resource libraries to import and export data from varied systems into Cloud infrastructure and back, along with its event mapping techniques which helps the data consumers to pinpoint the precise data that is required for such analysis.

Scenario #3 Multiple research centers have databases containing research information related to Ovarian Cancer, and one of these centers needs to perform a meta-analysis that incorporates data from all the centers. The meta-analysis helps understand the oncogenomic, disease progression, and treatment resistance, that will help researchers and clinicians to develop molecules and implement a sound treatment decision support system. How can these centers create a shared environment to access metadata for analysis without creating a large data infrastructure?

Alignment on data format, data exchange, and application of hypothesis and experimental conditions to clinical data needs attention. This expedites the process workflows and helps new members to understand the data, FHIR enablement is the answer to all the questions.

The above scenarios call out the three pillars of FHIR *A). Integration, B). Interchange, C). Interoperability*

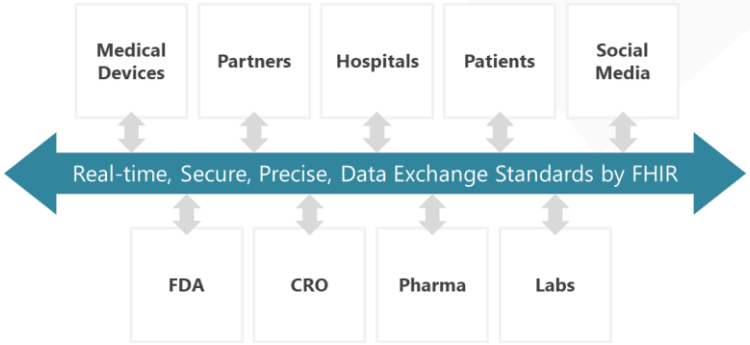

Fig. 3 – Areas of impact in Life Sciences

REGULATORY PERSPECTIVE

- On January 18, 2019, the USFDA came out with data standards program and action plans, and looks forward to align its goals with HL7 FHIR standards in three key areas which are as follows:
  - Pre-market strategies
  - Post-market outlook
  - Innovation
- It has focused its FHIR initiatives on unstructured data, Standard for Exchange of Nonclinical Data (SEND), mapping and integration of Biomedical Research Integrated Domain Group (BRIDG) to FHIR, and data collection into EDC from EHR in clinical trials through interoperable measures using FHIR.
- All these infrastructural standards require FHIR capabilities which will enable pharma/CROs and other life sciences organizations to break down information silos and drive seamless data exchange.
- Going forward USFDA aims to provide its commitment to EMA on the use of FHIR in clinical and non-clinical data exchange among different systems for pre- and post-market product development.

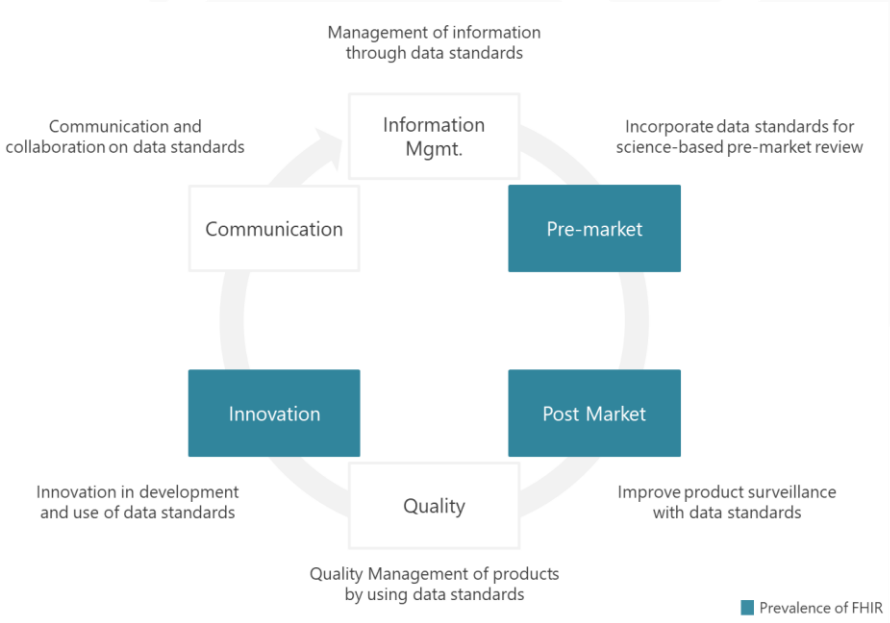

Fig. 4 – USFDA Data Standards Strategy Goals

CONCLUSION

- Life sciences organizations have been seeking secure data standards and exchange platform to create an ecosystem for standalone systems to exchange critical data in real-time.
- The proliferation of wearables, big data, and clinical / non-clinical data from point-of-care and patients has accelerated the need for faster adoption of robust data exchange standards.
- FHIR will enable organizations to develop data exchange platforms for EHR to EDC and eSource.
- Increased demand of clinical trials to be more pragmatic and the need for informed decision-making process in pre- and post-market strategies using real-world data and evidences has further pushed the need for FHIR.
- FHIR can solve a major hurdle of security and confidentiality of PHI (Patient Health Information) and Company Confidential Information (CCI). FHIR standards provide the flexibility to create apps and reusable components that can be easily plugged in for real-time data exchange.
- Regulatory bodies such as USFDA and EMA are continuously working towards integration of their systems with FHIR standards for minimizing the efforts needed for managing life sciences workflows and increasing ROI.

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