

Single Day Event

REST APIs in Clinical trials and Programming evolution

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- ❑ From where we are currently....
- ❑ To where we want to be....
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- ❑ Any blockers in using REST APIs for CT and/or Programming delivery?
- ❑ Short stint on CDISC/Transcelerate DDF initiative

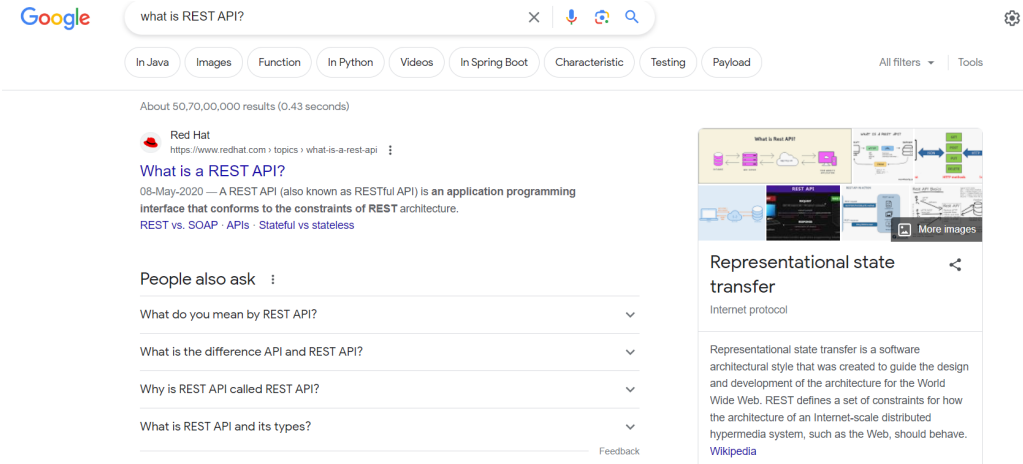


Do we know what is RESTful APIs?

- ❑ HTTP protocol
- ❑ REST server provides access to “resources” identified by URIs/Global Ids
- ❑ JSON is the USP for REST APIs

Most common HTTP methods used in the REST architecture viz:

- 1) GET
- 2) POST
- 3) DELETE
- 4) PUT

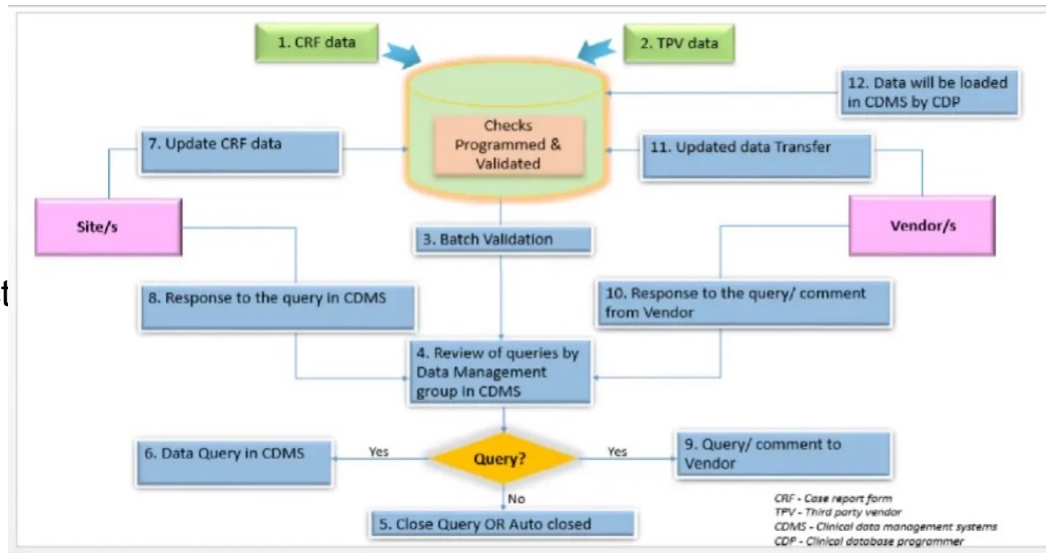


Sr.No.	URI	HTTP Method	POST body	Result
1	/UserService/users	GET	empty	Show list of all the users.
2	/UserService/addUser	POST	JSON String	Add details of new user.
3	/UserService/getUser/:id	GET	empty	Show details of a user.

From *where we are currently*....

■ Some known facts.....

- 1) DB Go-Live getting delayed due to DTS not being final...(really annoying... ☹)
- 2) Ripple effect on timelines, resource and above all, cost of the trial conduct
- 3) Average time to get clean data since the data entry: **approx.30 days**
- 4) **3rd party data Vendor reconciliation** is the rate limiting step
- 5) DB unlocks
- 6) MAP/SAP not defined as per program/protocol due to oversight leading to amendments



- 7) Recalculation of study power, sample size and recruitment timelines
- 8) Delayed analysis- jeopardizing safety & efficacy data analysis



To where we want to be....

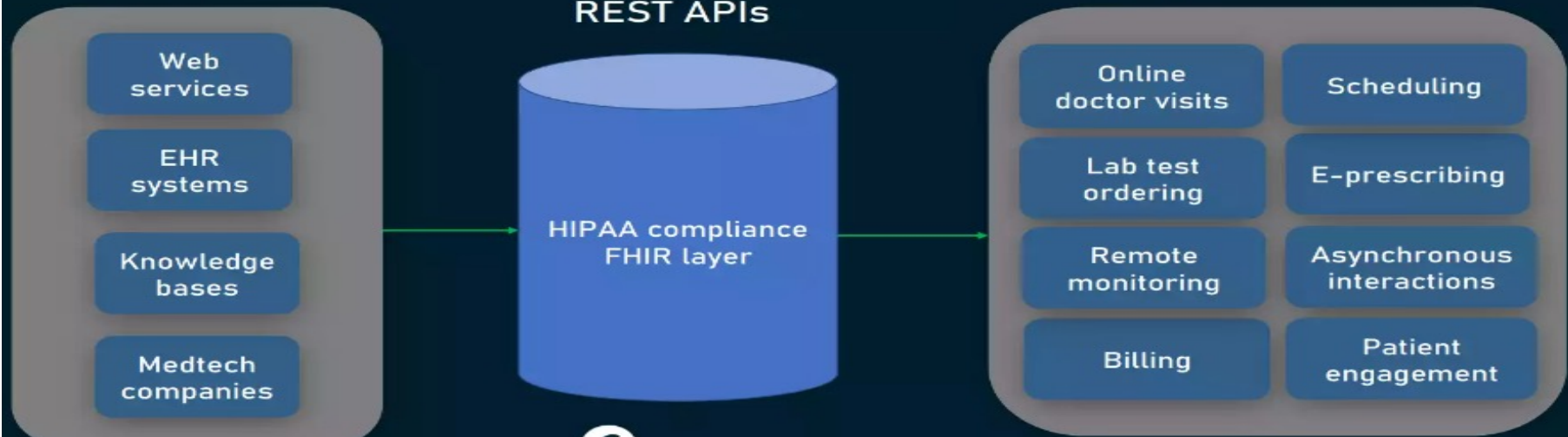


APIs and telehealth solutions

API providers

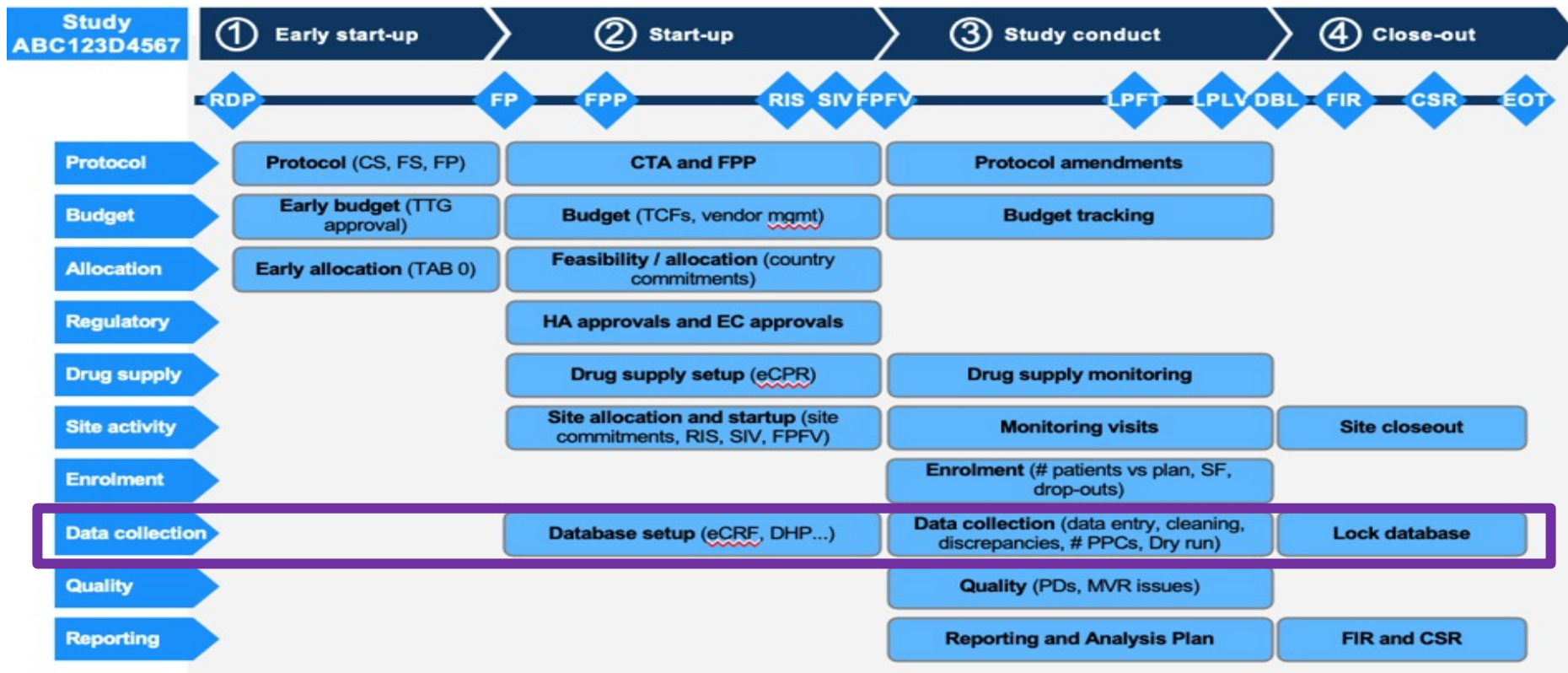
REST APIs

Remote services





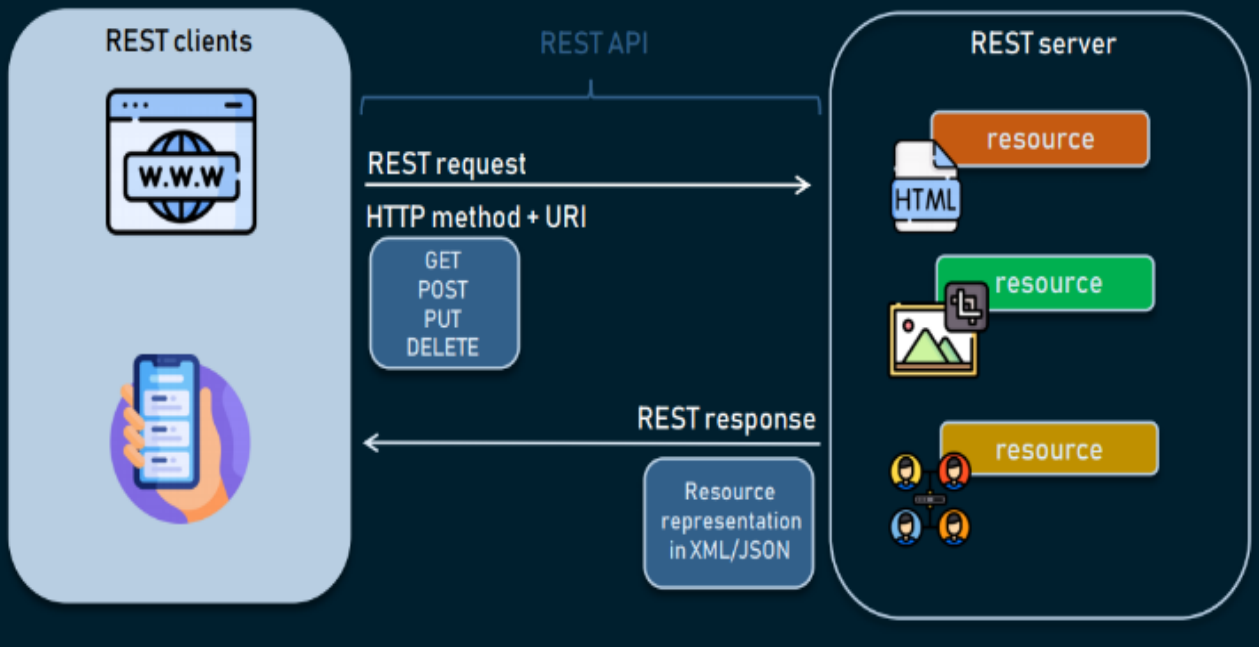
To where we want to be....





Applications / Use-cases in Clinical Trials(CT) and programming for RESTful API

REST API IN ACTION



Data Exchange:

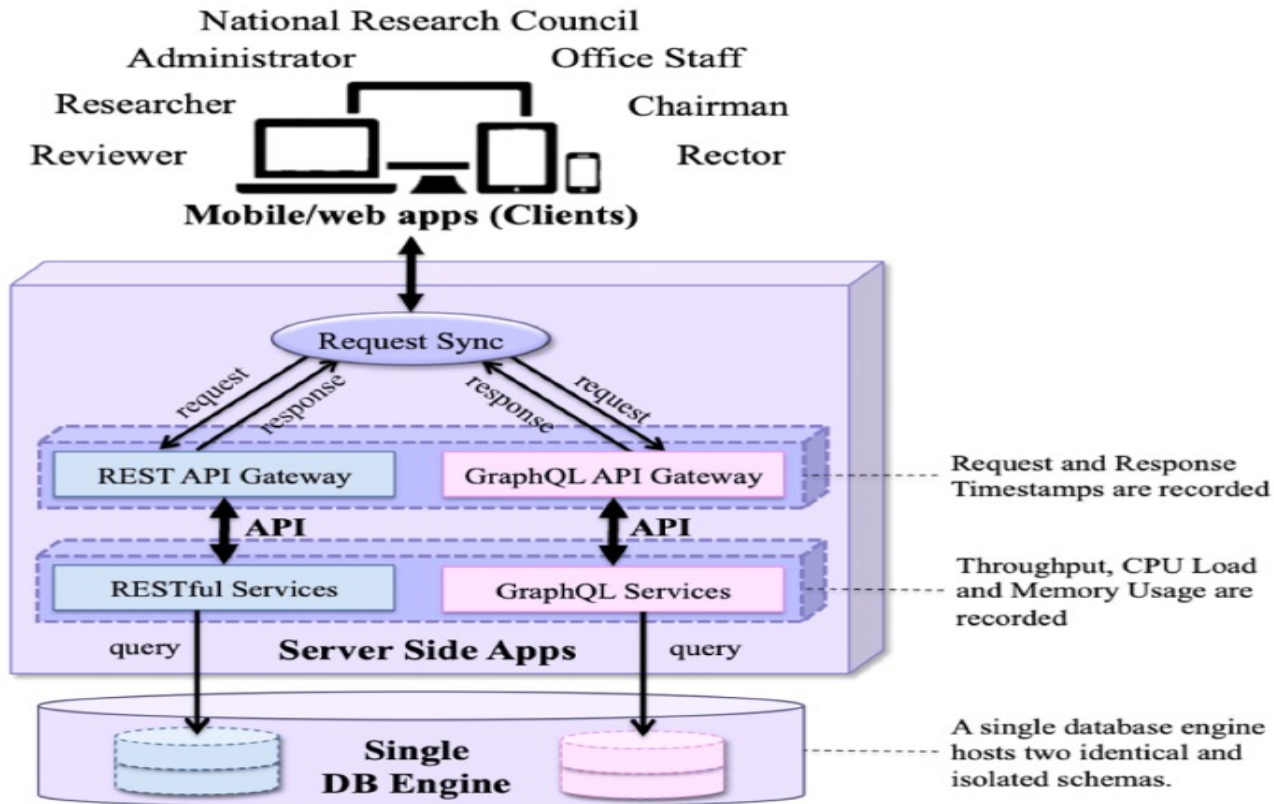
- Reduces **DTSS** dependency and enhances **operational efficiency**
- **EDC system- patient level** → CTMS
- 3rd party data reconciliation on the fly with validation
- Internal data interoperability(*GxP compliant standards*)



Use-cases....

Querying Data:

- Query through **specific data elements** - - - -> **clean** data
- EDC system – **query patient level data** - - standard responses
- Pre-defined data elements---**clean** real-time 3rd party vendor data reconciliation

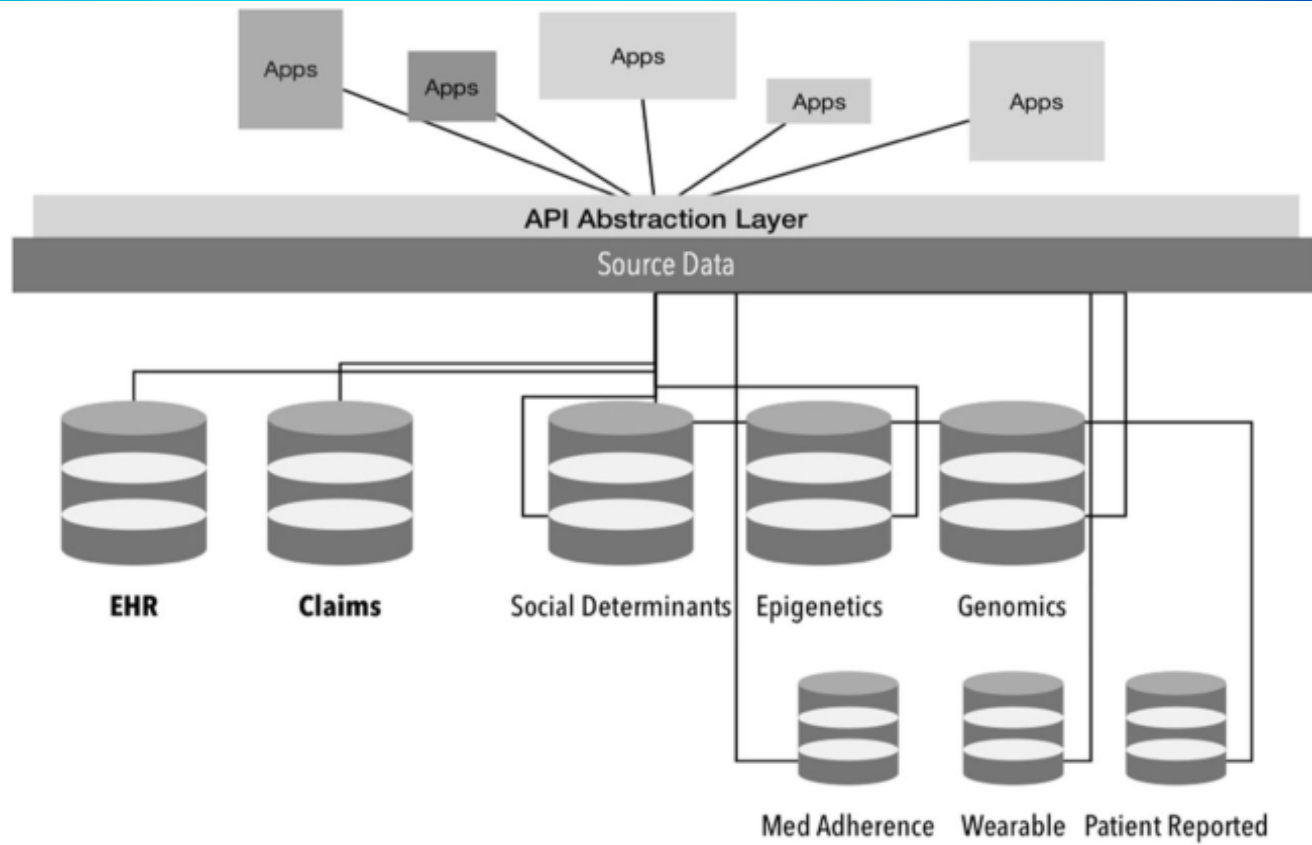




Use-cases...

Patient Recruitment:

- Integration with ext. platforms (**PRD**-recruitment databases/ **CT listing services**)
- Noises are eliminated
- Filtering I/E criterions
- Increase **~50% recruitment rate**

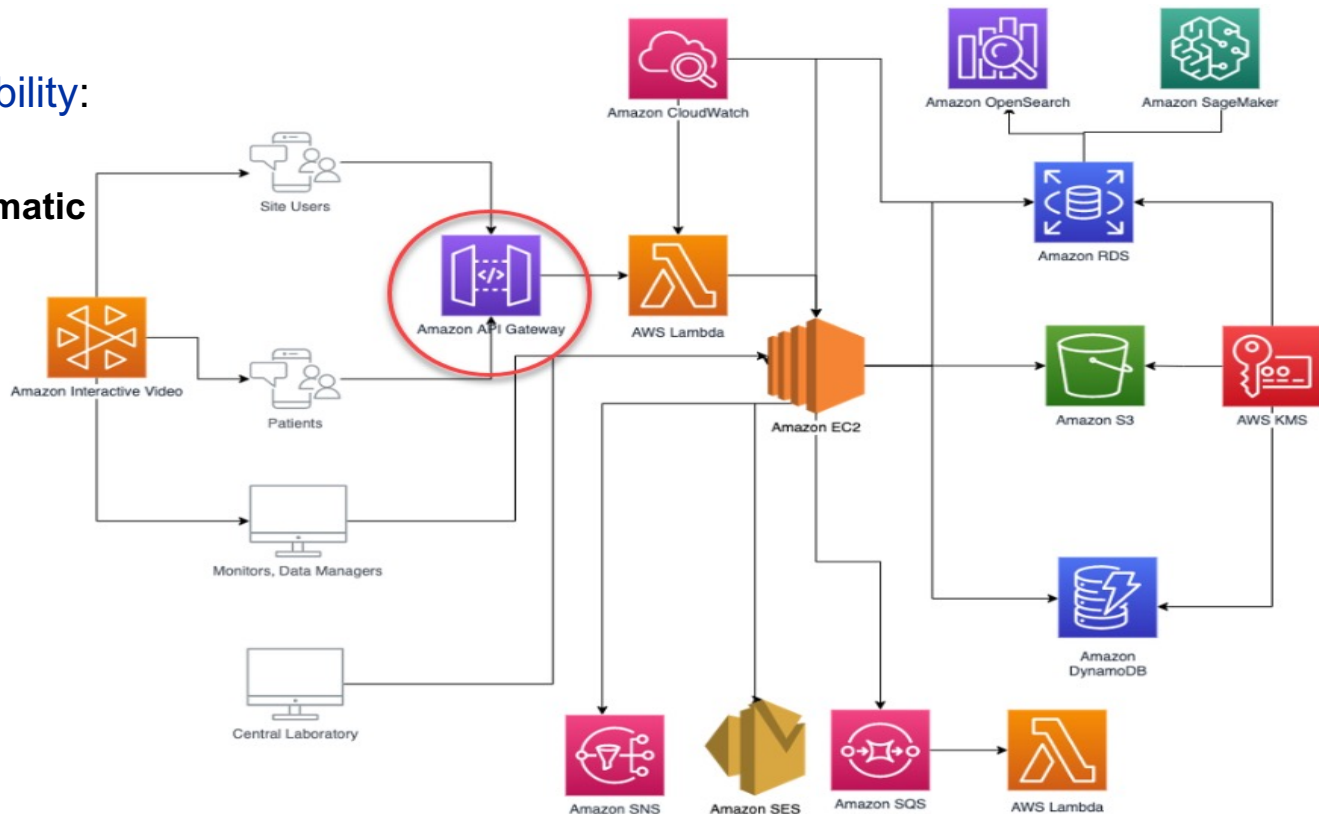




Use-cases....

System automation/interoperability:

- Endpoints- **[programmatic access]**-CT systems
- Custom applications/workflows
- **Eliminates** manual intervention
- **40% efficiency gain**-programming





Any blockers in using REST APIs for CT and/or Programming delivery?

Data Security and Privacy Concerns:



REST APIs require robust encryption, authentication, and authorization mechanisms for security



Interoperability Challenges:
overcoming mismatched formats, varying standards etc



Legacy Systems: challenges in integrating legacy systems with modern REST APIs



Regulatory Compliance:
complex implementation for clinical trials

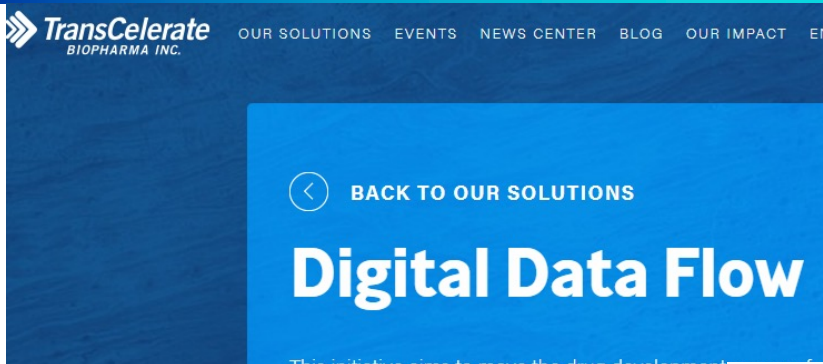
Data Volume and Scalability:



Inadequate scalability could lead to performance issues



Short stint on CDISC/Transcelerate DDF initiative



Home / Digital Data Flow

Digital Data Flow

Overview Participate Webinar Release Information Fil

Published Date: 27 June 2023

CDISC is collaborating with TransCelerate as a part of [TransCelerate's Digital Data Flow](#) standard model for the development of conformant study definition technical Implementation. Additional information can be found on the [TransCelerate](#)

Digital Data Flow - Phase 1 (July 2021 - July 2022)



Short stint on CDISC/Transcelerate DDF initiative

The Digital Data Flow Initiative (DDF) aims to catalyze digital transformation; breaking the document paradigm to enable seamless flow of the data within

Digitized Protocols

Enabling the use of technologies that identify and assemble study elements allows industry to move to digital protocols

Advanced Analytics

Better enabling the use of advanced analytics such as Artificial Intelligence and Machine Learning to improve study designs



Connectivity of Data and Processes

Enabling traceability, automated flow of content to key clinical documents, and automation to clinical & operational systems (e.g.. EDC, CTMS)

Open and Flexible Solution

Developing a dynamic, fully automated solution that is vendor agnostic, open and flexible

Development principles to enable broad collaboration, stakeholder input, and sustainability



Open Source



Vendor Agnostic



Agile Development



Dynamic Alignment
to Standards





The Global Healthcare Data Science Community

Contact Channels

- 📞 UK +44 1843 609600
- ✉️ office@phuse.global
- 🌐 phuse.global

Social Media

- 🐦 [@phusetwitta](https://twitter.com/phusetwitta)
- 📘 [/phusebook](https://facebook.com/phusebook)
- ▶️ [/phusetube](https://youtube.com/phusetube)
- 🌐 [/company/phuse](https://linkedin.com/company/phuse)



Back-up Slides

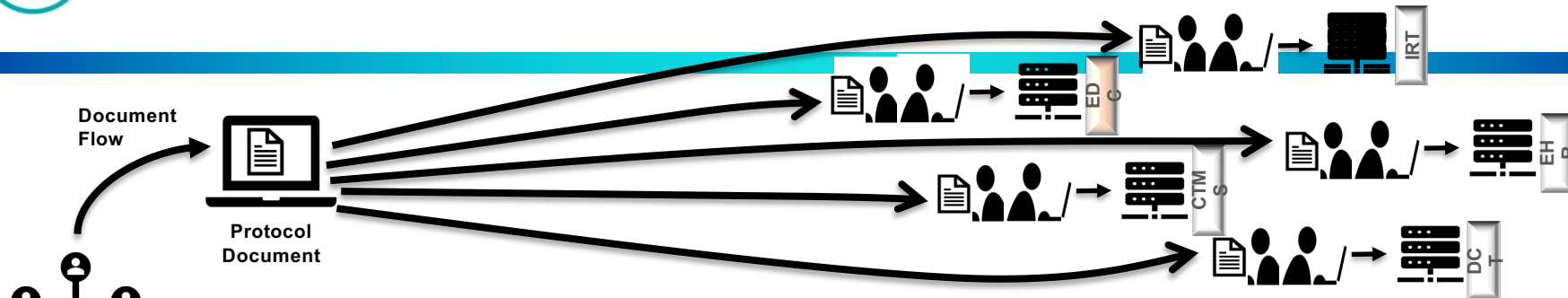




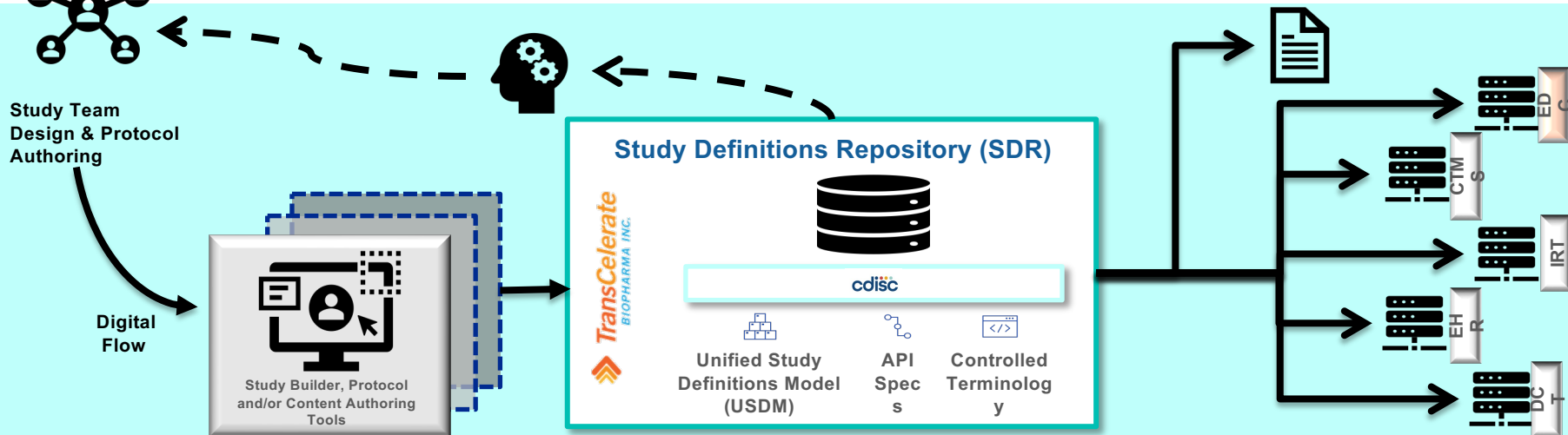
Clinical Study Protocol – Digitization & Data Flow

Enabling Downstream Automation and Analytic Insights

Today



Tomorrow





The diagram illustrates the Activity lifecycle and its JSON representation. The lifecycle flow is as follows:

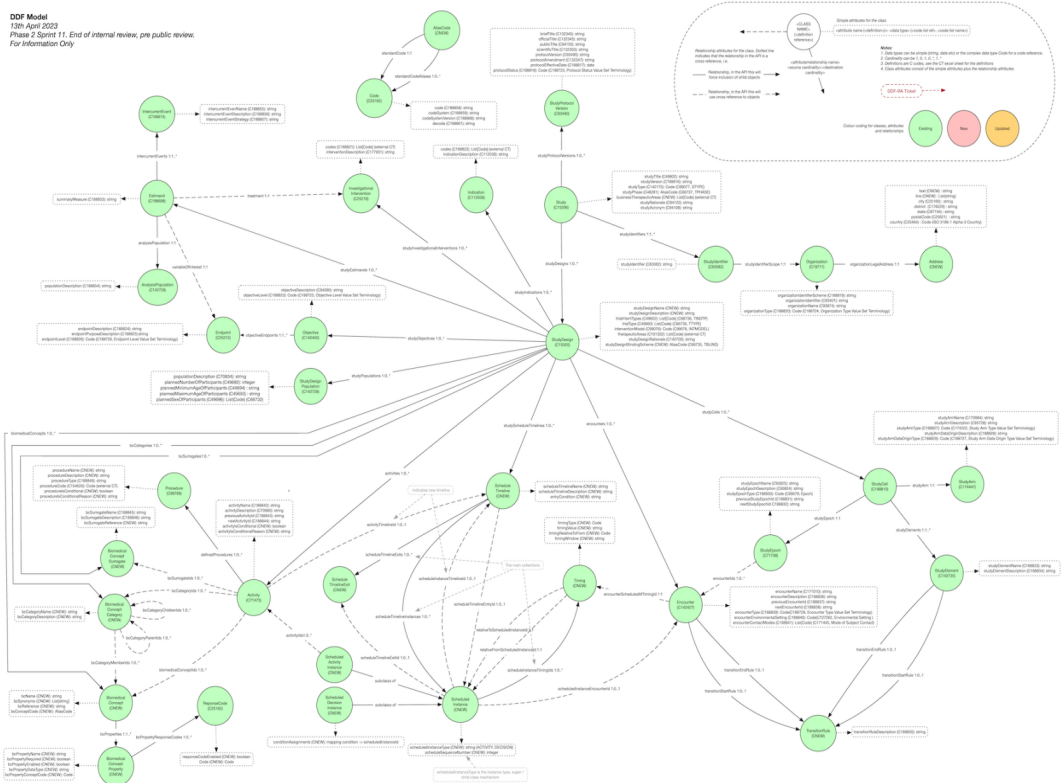
- Schedule Timeline** (grey rounded rectangle) leads to **Scheduled Activity instance** (blue circle).
- Scheduled Activity instance** leads to a small white square node.
- The small white square node leads to **Scheduled Activity instance** (black circle).
- Scheduled Activity instance** (black circle) leads to **Schedule TimelineExit** (grey rounded rectangle).
- Scheduled Activity instance** (black circle) also leads to **Encounter** (red circle) and **Epoch** (red circle).
- Encounter** and **Epoch** are linked by a red arrow pointing from Epoch to Encounter, labeled "Added during public review".
- Scheduled Activity instance** (black circle) leads to **Activity** (green circle).
- Activity** (green circle) leads to **Activity** (green circle).
- Activity** (green circle) leads to **BC** (green circle) and **P** (green circle).

The JSON representation of the Activity is shown below:

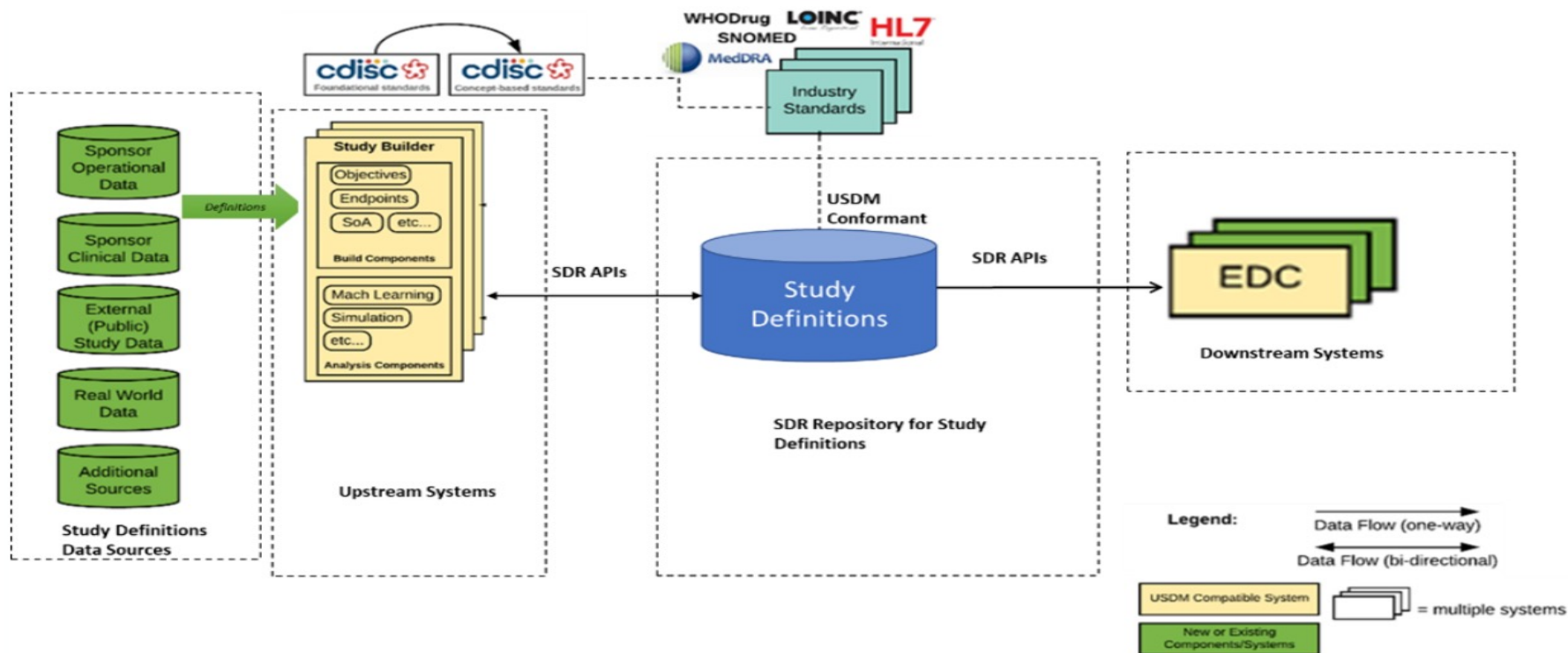
```

uncId": "ScheduledActivityInstance_1",
uncType": "ACTIVITY",
uncExitId": null,
uncTimings": [...],
uncTimelineId": null,
idId": "ScheduledActivityInstance_2",
edyEpoch_1"

```



Short stint on CDISC/Transcelerate DDF initiative



FOR MORE INFORMATION



**Exploration by technology
solution providers, sponsors, CROs
welcome**

*Visit the DDF GitHub site by
scanning the QR code*

Phase 2 of development
Q4 2022 – Q2 2023