Hyperledger Community HLHC SIG Patient Subgroup Patient Consent

20191213

Team presentation

Team ☺ order with the daybreak - since July 2019

Deniz

Kent Lau Domain

Pharma & Clinical Trials

https://www.linkedin.com/in/kentglau/

Anil Srikantiah

SW – Fabric

https://www.linkedin.com/in/anilsk/

Grigoriy Zhovnuvaty

SW - Sawtooth

https://www.linkedin.com/in/grigoriy-zhovnuvaty-aa102679/

Deniz Coskun

Lead

https://www.linkedin.com/in/deniz-coskun-phd-a09a002/79/

John Walker

SW – Fabric

https://www.linkedin.com/in/john-walker-32b40117/

Alexander Zhovnuvaty

SW - Sawtooth

https://www.linkedin.com/in/alexander-zhovnuvaty-88004026/

Ihor Zhuchenko

Medical & Clinical Trials

https://www.linkedin.com/in/ihor-zhuchenko-9a63354b/

Patricia Buendia

Medical & SW

https://www.linkedin.com/in/patricia-buendia-healthscience/

https://github.com/hyperledger-labs/patient-consent

Challenges in Healthcare: Compliance

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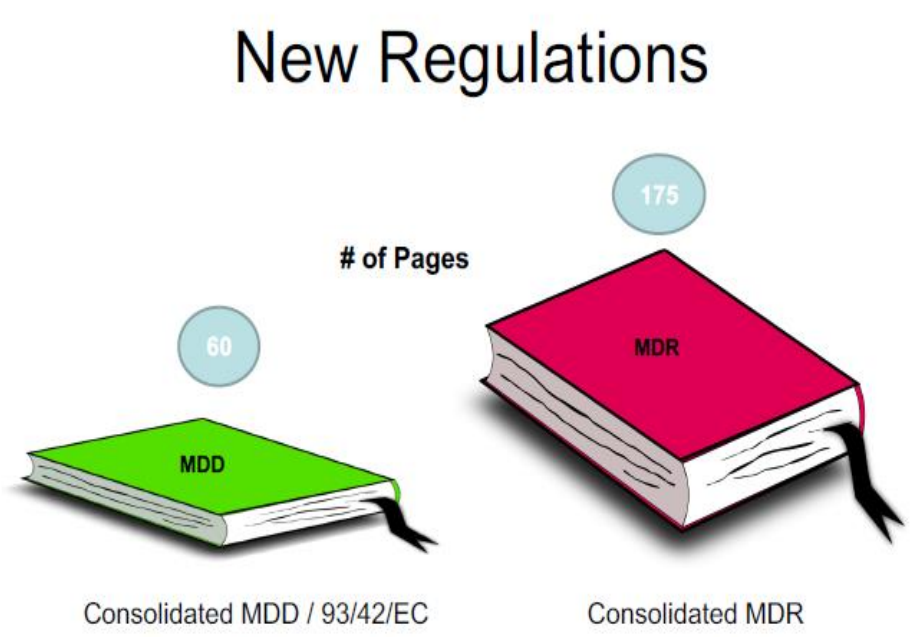
For the all industries and services

Higher Regulations for Medtech Providers



= Longer time2market and Development costs

Pain points for Medtech and Pharma: Focus Clinical Trials

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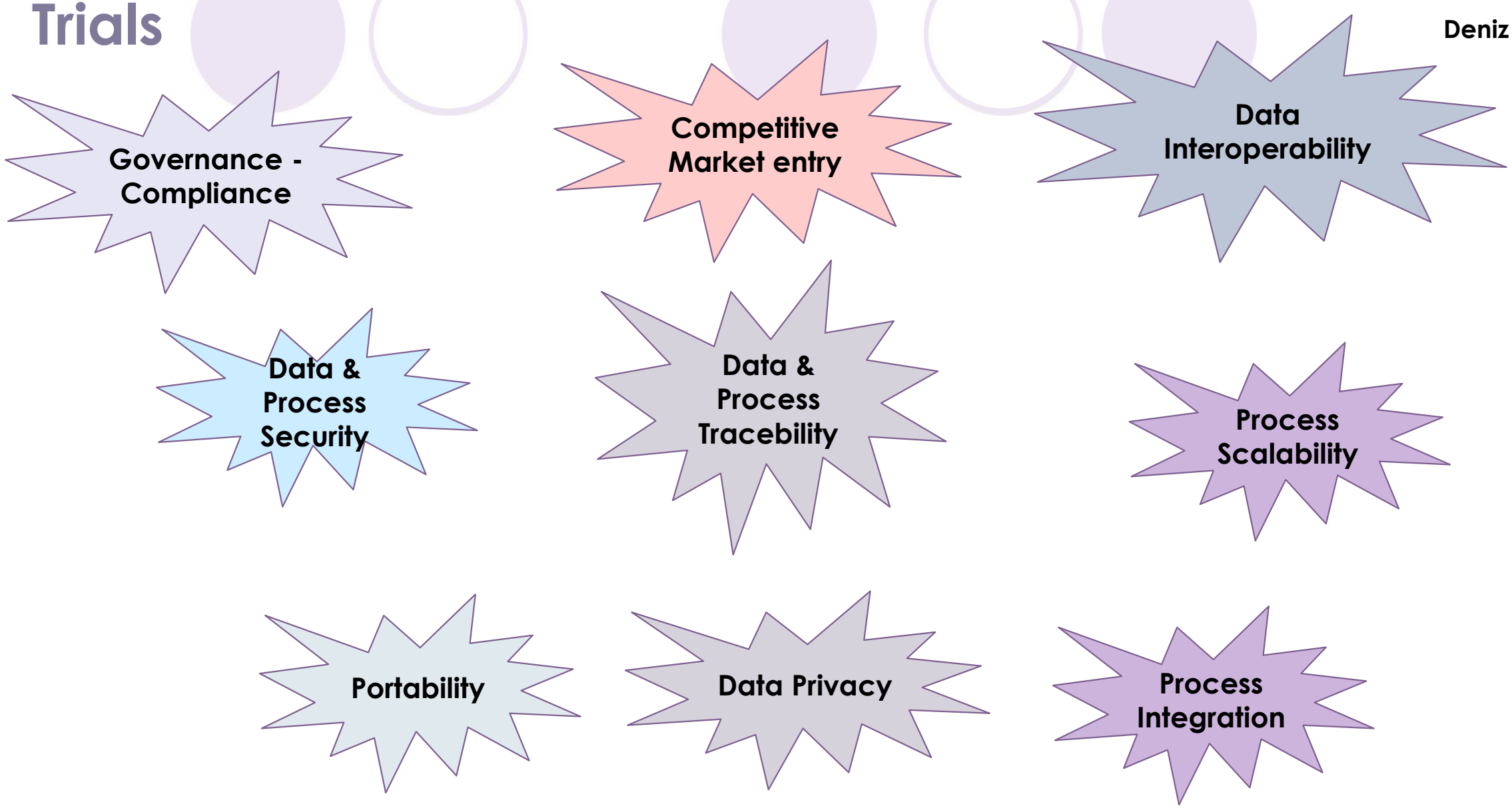

Clinical Trials: A complex and distributed process with great amount of data flow

Ihor

	Laboratory Phase	Phase 1	Phase 2	Phase 3	Phase 4 (On the market)
Why?	• Find the safe dosis • Test on the mices • Impacts	• Healthy individuals • Find the safe dosis on humans • Way to take the drug • Monitor the Impacts (side effects)	• Find the safe dosis on humans • Effects on certain diseases • Monitor the Impacts (side effects) • Divided in different populations • Placibo control	• Which dose is the most effective in Phase 2 • Compare the new drug or use with the standard treatment • Monitor the Impacts (side effects) • Placibo control	• Long term safety and effectiveness • Monitor the Impacts (side effects)
Number of patient - total		One site 10 patients	< 800	1000 – several 10000	1000 – several 10000
Number of sites		1 site for rare disease - Min 2 to keep two different views – (up to 10 sites)	Up to 80 sites	Up to 100 sites	Up to 100 sites
Duration (years)		Up 2 – 3 years(only in US)	2 - 5	2 - 5	1 - 3
Documentation (relevant doc`s for consent)		Protocol1 + consent form1	Protocol2 + consent form2 + (versions)	Protocol3 + subprotocols3`s consent form3 + (versions)	Protocol4 + subprotocols4`s consent form4 + (versions)
Protocol changes?		No big changes	1- 2 times	3 – 6 times	2 – 5 times
Requests (times)					
Approvals (times)		Approval at the beginning * (site) + protocol changes * (site)	Approval at the beginning * (site) + protocol changes * (site)	Approval at the beginning * (site) + protocol changes * (site)	Approval in the beginning * (site) + protocol changes * (site)
Consent (times)		Initial consent (20 – 80) + (protocol changes * patient number)	Initial consent (800 – 5000) + (protocol changes * patient number)	Initial consent (1000 – 10000) + (protocol changes * patient number)	Initial consent (1000 – 10000) + (protocol changes * patient number)

Clinical Trials: We want to accelerate the flow Question: Integration with the legacy systems?

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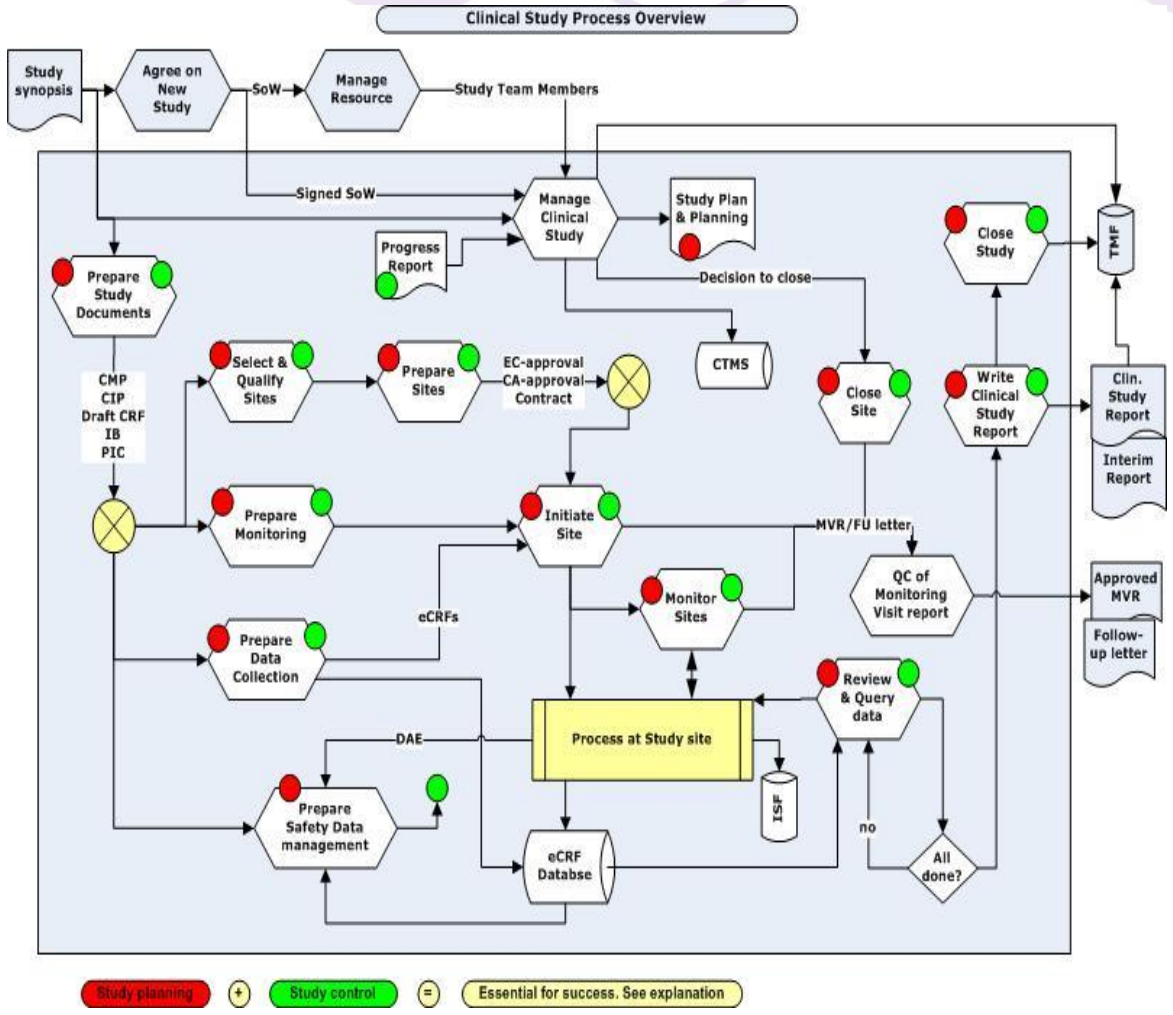

- Clinical Trials Workflow?
- Which process we need the most?
- Which protocols and API-Standards we can define?
- Which CTMS`s can be integrated? Veeva, Medidata, Informa, Oracle?

The solution?

Solution is Enterprise Blockchain.

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Why we need Enterprise Blockchain in Clinical Trials?

We provide with our Use Case

- ➔ **High process validation efficiency for regulators**
- ➔ **Low cost process and defined governance**
- ➔ **Provide GDPR Compliance, security and data protection**

- ➔ Consolidate and integrate the distributed landscape ecosystem
- ➔ Close the open-end processes between stakeholders - ledgers

Results:

- ➔ **Better Compliance with Trial Governance** with the blockchain
- ➔ **Security** through cryptography
- ➔ **Build trust and automation** with smart contracts
- ➔ **Transparency** with transactions
- ➔ **Traceability** with blocks
- ➔ **Immutability** with blocks
- ➔ **Integration of stakeholders** with the distributed ledger architecture

Higher value to sponsors, investigators and patients centric trials to accelerate the clinical trial process

Two examples:

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1. Increased efficiency of regulatory approval in Clinical Trials:

Compliance and quicker regulatory approval →

USD$ 17 million revenue per extra day saved while on patent monopoly.

Twenty-four billion dollars from 1,393 days of patent extension and pediatric extension on Lipitor. This is the additional revenue which Pfizer received from sales between May 30, 2006 (when its primary patent on Lipitor would have expired) and March 24, 2010 (when its patent term and pediatric extensions expired.

https://www.healthaffairs.org/do/10.1377/hblog20160913.056548/full/

1. Clinical Trials in oncology:

- Trial duration of between
- 15 to min. 10 years,
- in which one day at CRO costs 15000 USD min,
- and patient data from 5000 to 25000 USD

15 years * 220 days * 15000 USD/day and 5000 USD * 10000 patient data (min) = 49,5 millions + 50 Millions = 100 millions USD for only one trial 8in this trial we need to calculate few other positions), and you need multiple trials for one drug

Most importantly, the time2market before the other competitors.

- With our Use Case you can save min. 25% of the efforts and the time for the clinical trials. If you improve:
- Compliance and scalability of the clinical sites
- Leverage for the virtual trials
- Integration with patient data

https://www.frontiersin.org/articles/10.3389/fbloc.2019.00023/full

Our value proposition is;

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- We use the **existing technology** for the **existing challenges** to develop **non-existing patient centric solutions**, that uses Blockchain, Artificial Intelligence, IoT, and most important with the **domain knowledge**

- Patients will get a better visibility on the available clinical trials and will be able to manage their consent in a very simple way but most importantly in a secure and immutable way (blockchain).

- The benefit for the Pharma Companies, Medtech`s is a considerable reduction of time and costs compared to the standard process. Additionally, our service allows the users to optimize their patient selection criteria to ensure that the desired number of patients will be available to potentially enroll in their clinical trial.

- The benefit for the patients is a better visibility of the available clinical trials which they might be able to join based on the patient selection criteria.

- We need collaborations with the expert user`s, industry to excel our solution, starting with E-Consent in Clinical Trial, and build the next blocks, Patient Recruitment and Clinical Monitoring

What is our target and our POC in details - 2020

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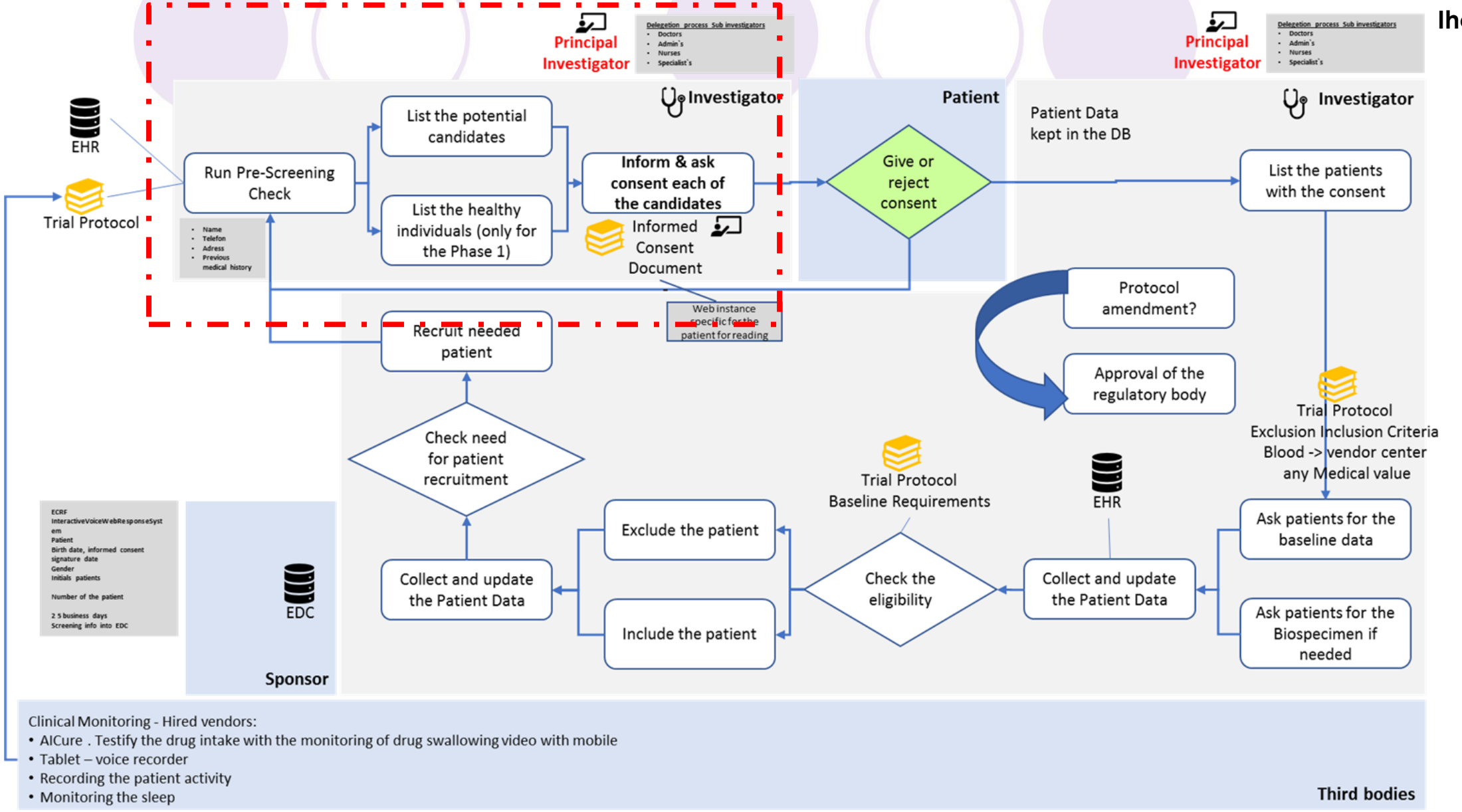
Use Case realizations with two frameworks, Hyperledger Fabric and Sawtooth, and benchmark with the defined criteria

- We assume that our investigator is a hospital with the patient initial consent and we have no other sites
- Trial Protocol: will be implemented as smart contract
- Protocol amendment and criteria definition: Initial protocol is included in consent management. The protocol may change during clinical trials based on adverse events and patient compliance. The patient will have to consent to the changed protocol.
- Consent Validation: After the consent we have the include and exclude criteria check

Use Case Scope: Econsent Scope Fix per 20191124

Ihor



Use Case Scope: Econsent Scope Mid of 2020

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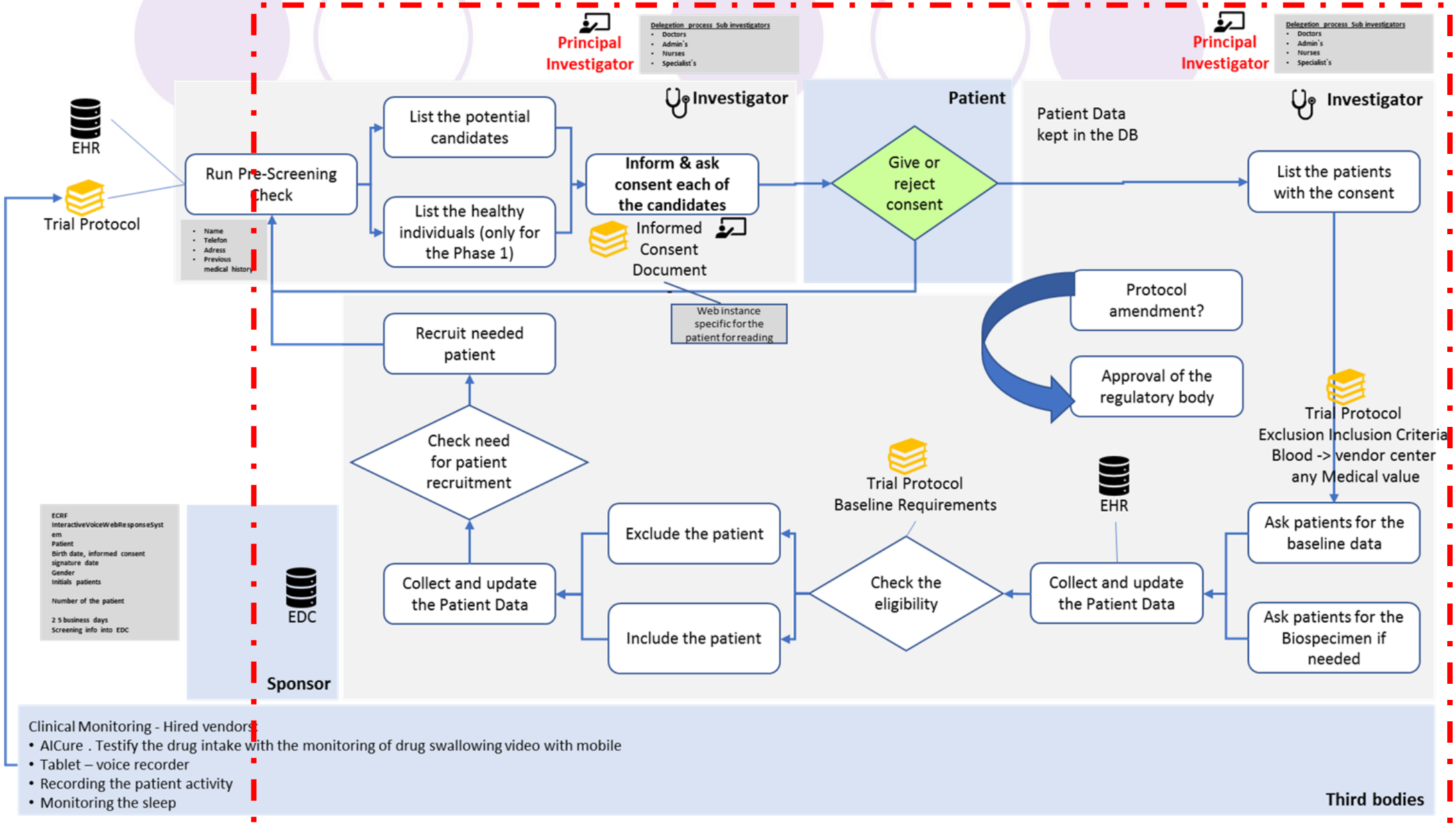

Target audiences;

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Pharma;

EU Member states:
Sanofi, Novonordisk,
BoehringerIngelheim

CH:
Roche, Novartis

India:
Torrent
http://www.torrentpharma.com/
Glenmark Pharma,
https://www.glenmarkpharma.com/
Jubilent Biosys
https://www.jubilantbiosys.com

UK:
GSK, AstraZeneca, Biogen

Investigators;

CH: 5 Big Canton and regional Hospitals

CRO`s

EU: Icon, IQVIA, PPD, PRA Health Sciences, MedPace

Patient Data Provider

CH: Clinerion
US: AmazonWebServices

Patient recruiters

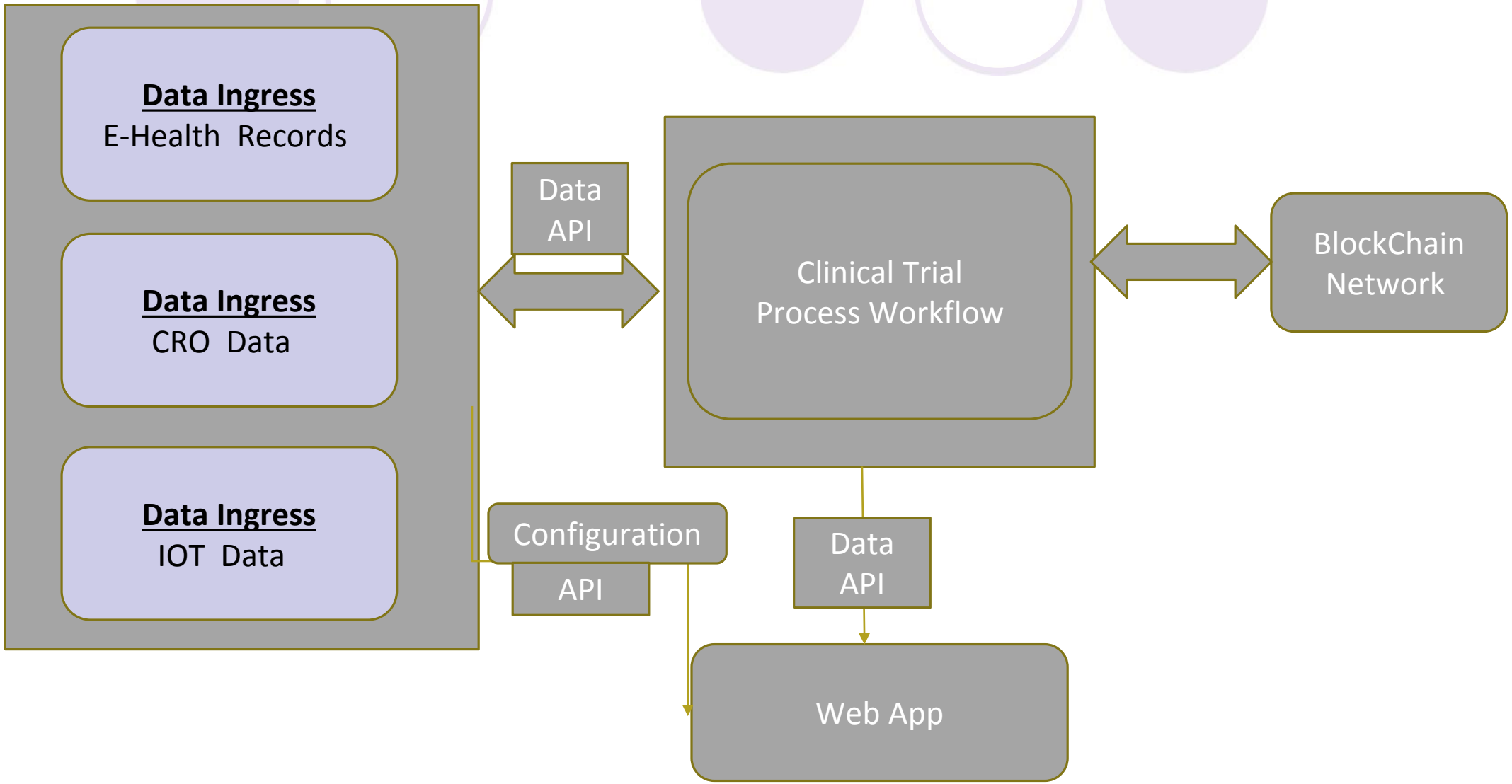
What are benefits for the Hyperledger Community

Kent

- Baseline and a viable POC for the next projects: like further Clinical Trial Integrations with Patient Recruitment and Monitoring
- Convergence of Hyperledger Components, Identity Management and API`s, Standardization of API`s and clinical trials components
- Comparison of two Hyperledger frameworks, Fabric and Sawtooth with one specific use case, pro`s and con`s, Benchmarking and Use Case Assessment
- Assessment and customization of use cases to the suitability of the solutions and possible improvement proposals
- Great motivation for the open source community for a portfolio of different ecosystem

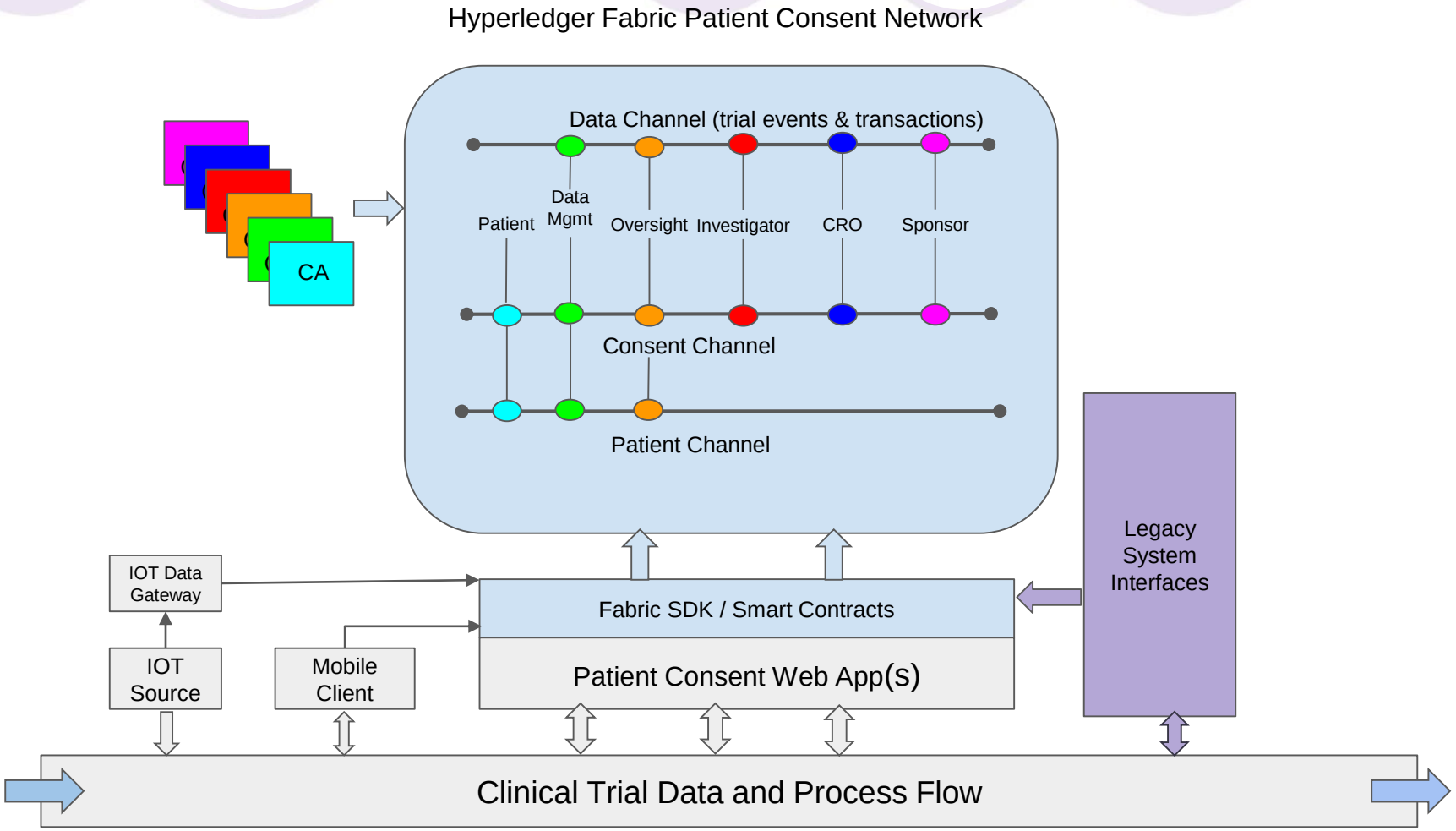
Solution: Big Picture for Clinical Trial

Alex



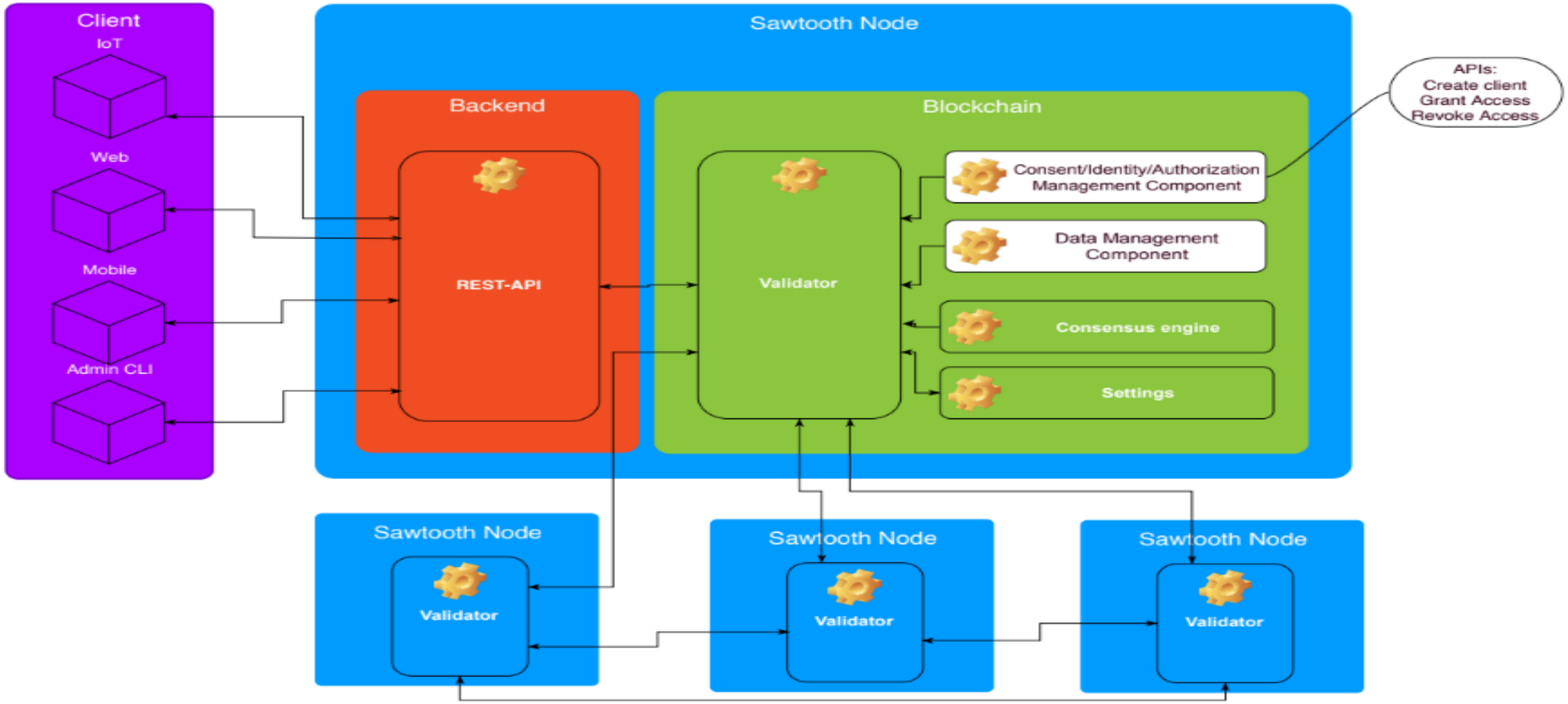
Vision: Hyperledger Fabric Architecture

John - Kent



Vision: Hyperledger Sawtooth Architecture

Alex



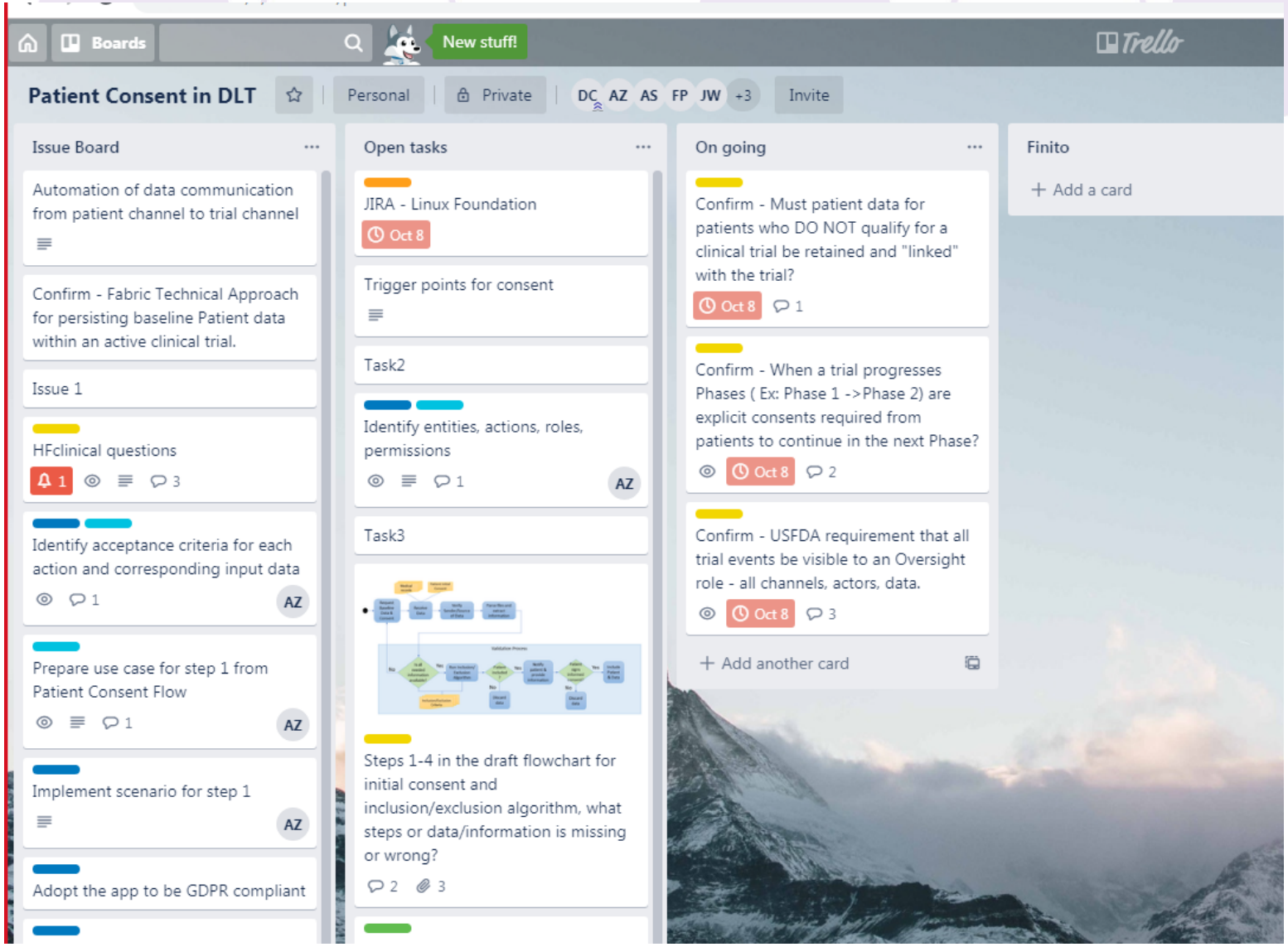
Demo with Hyperledger Sawtooth

Alex

Demo

Q & A

Annex: Ongoing work



Annex: – Benchmark Fabric 2 Sawtooth

- Use case realizations with two frameworks, Hyperledger Fabric and Sawtooth, and benchmark with the following criteria
  - Consensus algorithm
  - Applications nature
  - API`s and security
  - Transaction speed
  - Block interval
  - Block size
  - Communication protocol
  - Energy consumption per transaction
  - ?????
  - Applicability for use case – Functionality smart contracts, transactions, ledgers, consent,