

BLOCKCHAIN: The Game Changer in the Optimization and Efficacy of Clinical Trials

Live Broadcast:

Wednesday, 11 October 2017 @ 2:00 PM ET



MARIA PALOMBINI [MODERATOR]

Director, Communities and Initiatives Development,
GBSI, **IEEE-SA**

blockchain.ieee.org

WebEx Instructions for Participation

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the **IEEE-Standards Association**

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- 3** To ask **QUESTIONS** throughout the webinar, use the Q&A feature and send them to **Brett Houseal**.

Where can Blockchain Help with these Numbers?

\$359 MM

Company cost for development of **one** new drug from research lab to patient

12 Years

The time it takes a new drug to travel from the lab research to the patient (post-market approval).

10%

5 in 5,000 drugs that begin preclinical testing make it to human testing.

1

Only 1 of these 5 is ever approved for human consumption

Source: California Biomedical Research Association – <https://www.ca-biomed.org/pdf/media-kit/fact-sheets/CBRADrugDevelop.pdf>

\$8 MM

Lost revenue for **each day** a drug is delayed

Source: [Drug Development Technology](#)

≈ 3%

% of adult cancer patients participating in oncology clinical trials

Source: [National Center for Biotechnology Information](#)

80%

% of clinical trials that fail to meet their enrollment timelines

Source: [Drug Development Technology](#)

1

Only 1 in 20 of Americans know where to find information on relevant trials.
([CISCRP](#))

THE PANEL OF EXPERTS



VLADIMIR PETROVIC, Ph.D
Clinical Biomarkers and
Diagnostics, **Amgen**
www.Amgen.com



ROBERT BARKOVHICH
CEO & Founder, **Health
Linkages**
www.HealthLinkages.com



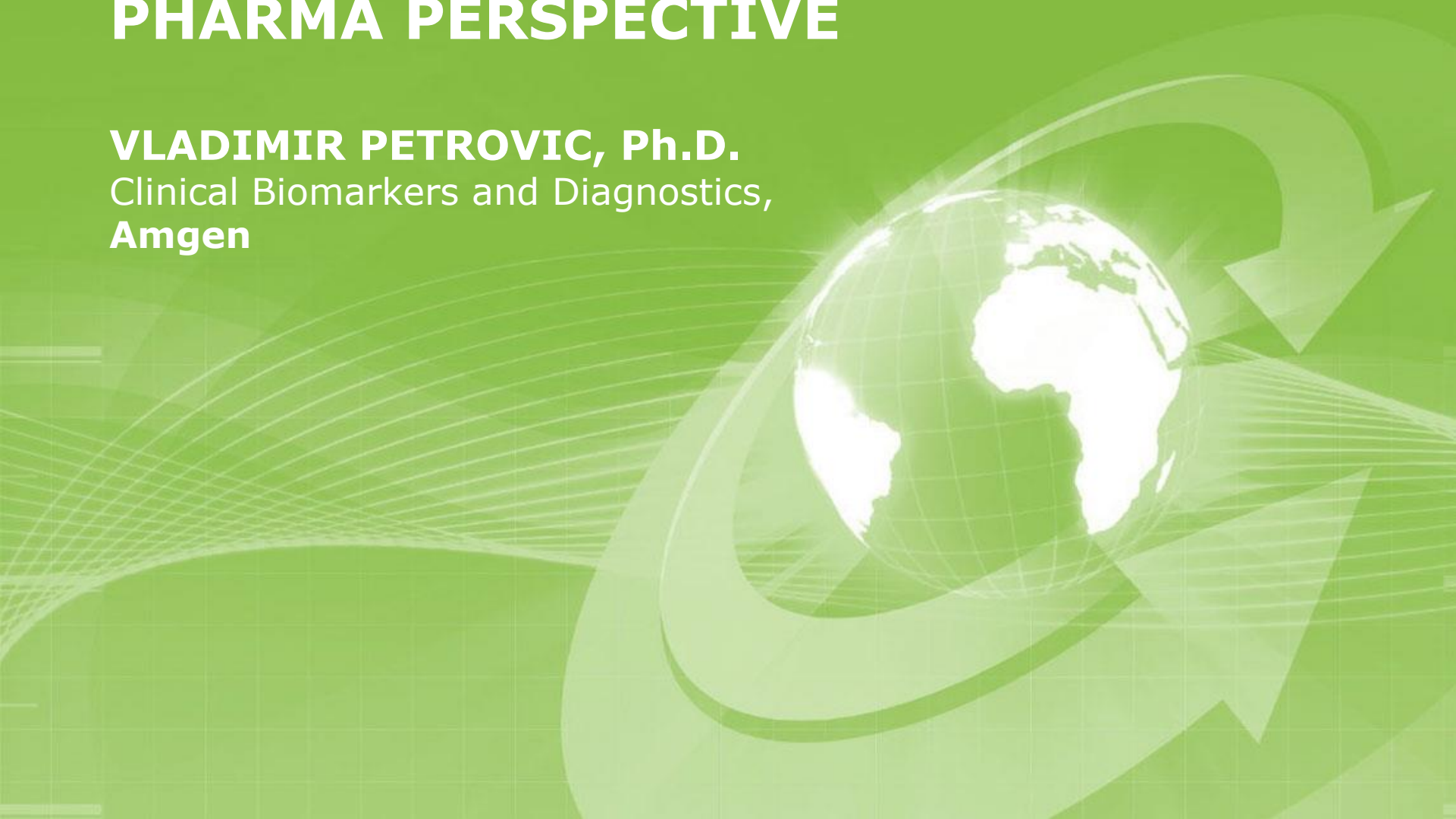
EDWARD BUKSTEL
CEO, **Clinical Blockchain**
www.ClinicalBlockchain.com

Key Learning Points of this Webcast

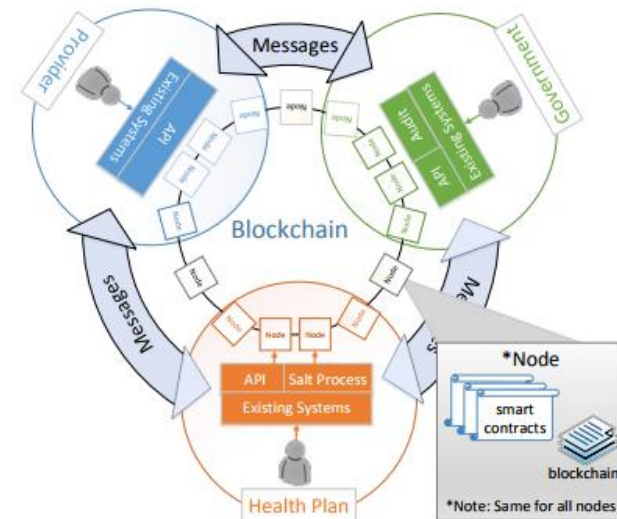
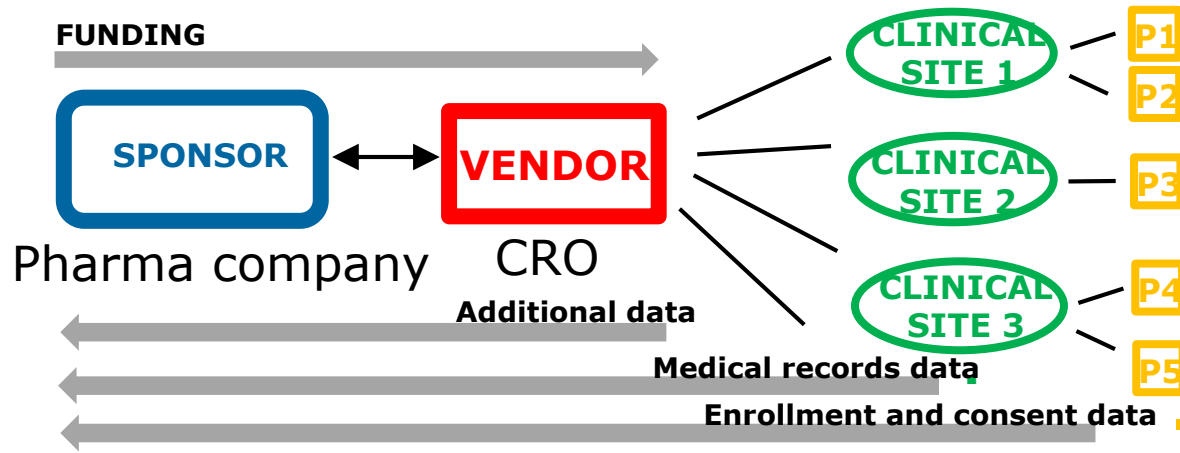
- Understand how blockchain technology can tackle the patient engagement/recruitment challenge
- How aggregation of health data from the blockchain can improve data analytics in assessing clinical trials outcomes
- Understand the difference between private and public blockchains applications in clinical trials
- How blockchain can close the gaps in clinical research that can accelerate drug development and improve patient safety and care

CLINICAL TRIALS & BLOCKCHAIN – A PHARMA PERSPECTIVE

VLADIMIR PETROVIC, Ph.D.
Clinical Biomarkers and Diagnostics,
Amgen



Clinical Trials and Blockchain



- \$14 billion market with ~90,000 registered trials
- A number of intermediaries
- Interactions/processes based on trust between parties

K. Culver: Blockchain Technologies: A whitepaper discussing how the claims process can be improved

Patient Recruitment and Informed Consent

- **Limited eligible patient population**
(only ~4% of US cancer patients enroll in clinical trials)
- **Securing identity**
Utilize cryptography to issue token/compute hash that anyone can check without revealing patient identity
- **Privacy concerns**
Portions of patient data can be accessed by different entities (access can be granted or revoked)
- **Capture events**
Enrollment can be posted on blockchain along with a minimal set of data
- **More reliable to report and audit**



<http://blogs.perficient.com>



www.fda.gov

Maintenance and access to electronic records (patient data)

- **Open-access data-sharing model**

- Streamlining data access is a complex issue
- System interoperability and accessibility
- Varying data standards
- Inconsistent rules and permissions



www.nysna.org

Blockchain could provide distributed framework to support access (not solve the issue by itself)

- **Data provenance**

- Manual data propagation/introducing human error
- Data exchange relies on emails or paper copies
- Audit trail is obscured and hard to follow



<https://sdr-uk.com/>

Blockchain can help with auditability but is not a substitute for enterprise database with high data volume

Bertagnolli et al., Advantages of a Truly Open-Access Data-Sharing Model, NEJM 23;376(12)

Data Generation and Integrity

Eliminating the need for trust between the Sponsor and the CRO

- CRO generated data (experimental measurements)
- Data analysis
- Complex pre-validated process with a strict set of rules
- Crucial for assessing drug efficacy, patient health and directing therapy
- CRO is contractually obligated to implement the rules



<http://epilepsyu.com>



<http://www.biotechlogic.com>

Blockchain can provide a checkpoint layer to ensure the rules are in effect and the generated data is intact

Advantages of Blockchain Inclusion

- The system for storing transaction records is distributed
- Network participants interact without establishing trust or central auth.
- Redundancy of stored information (size limit)
- Immutability of audit trail
- Enforcement of pre-agreed upon rules
- Real time accountability



<https://tradescript.com/>

Public vs permissioned blockchain

- Access: Open vs restricted (consortium)
- Security: Proof-of-work vs proof-of-stake
- Scalability: Number of transactions

Health Data Provenance

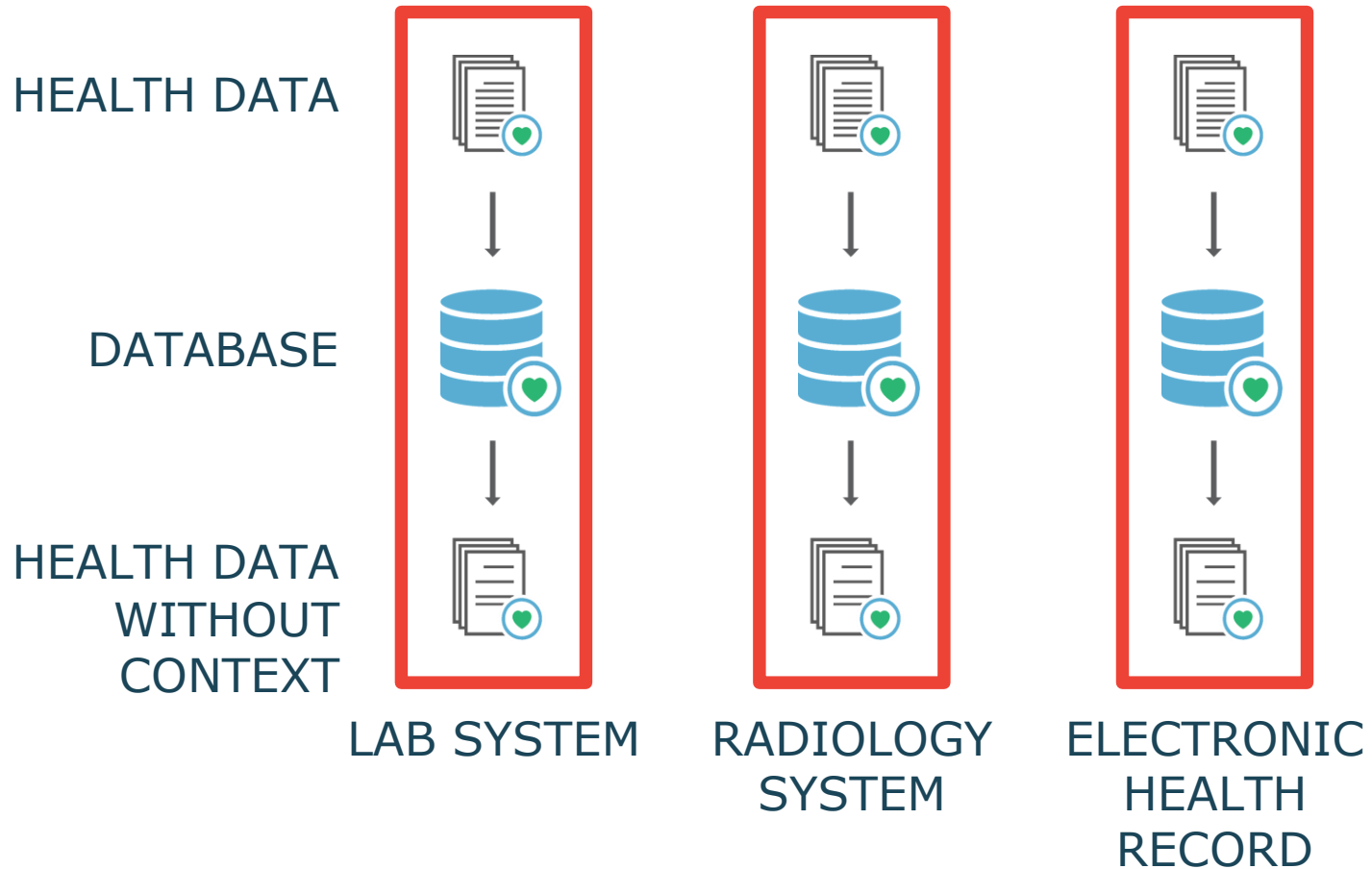
ROBERT BARKOVICH

CEO and Founder, **Health Linkages**








THE DATA PROVENANCE COMPANY™

CONTEXT IS ESSENTIAL



WHAT IS NEEDED

-  IMMUTABLE AUDIT TRAIL
-  DATA INTEGRITY
-  DATA SECURITY
-  DATA SHARING
-  DATA CONTEXT

EU GENERAL DATA PROTECTION REGULATIONS



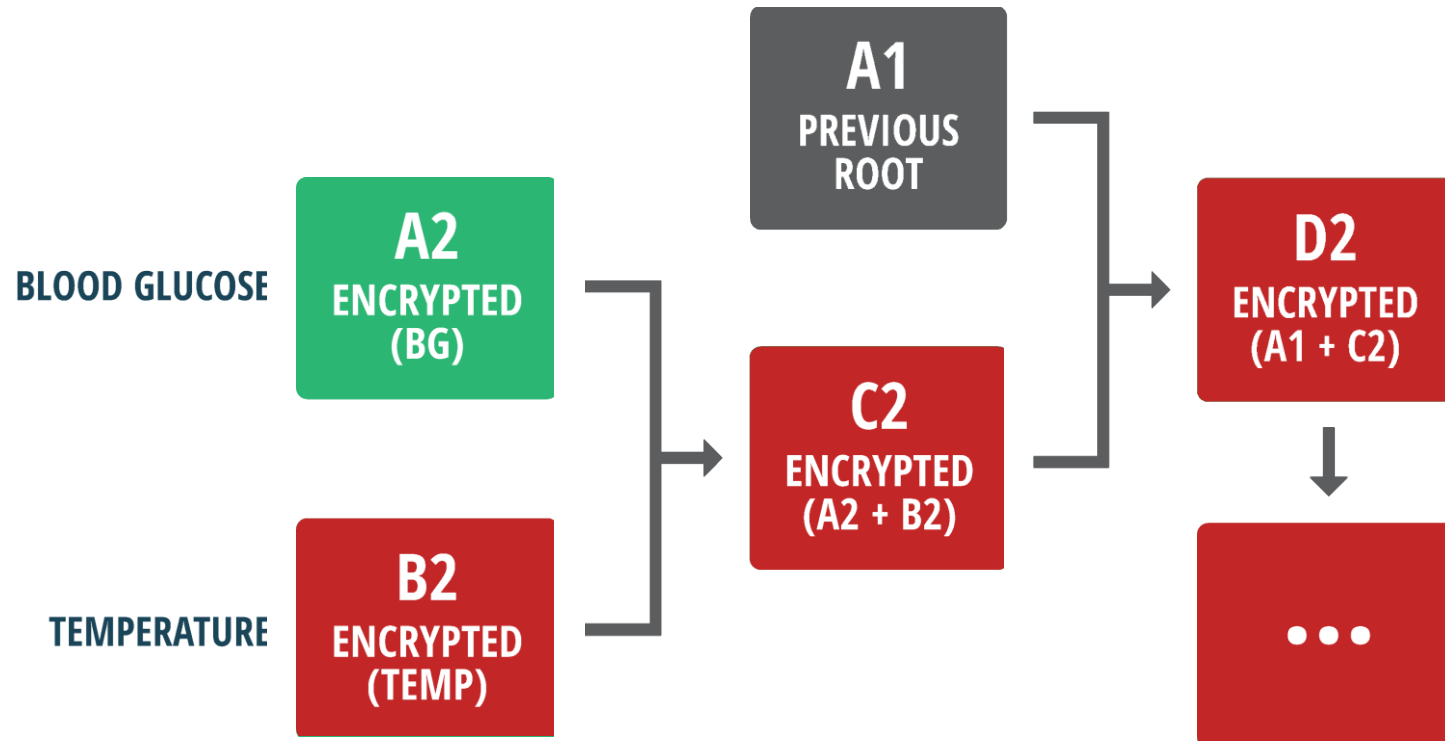
**ORGANIZATIONS
PROCESSING
PERSONAL DATA
OF EU CITIZENS**

REGULATIONS
INCREASED TERRITORIAL SCOPE,
BREACH NOTIFICATION DUTY,
RIGHT TO BE FORGOTTEN,
DATA PORTABILITY,
RIGHT TO ACCESS,
CONSENT,
PRIVACY

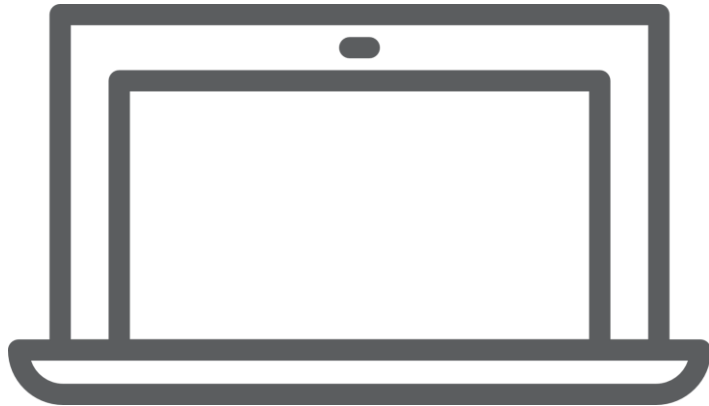
ENFORCEMENT: MAY 25, 2018

<http://www.eugdpr.org/the-regulation.html>

BLOCKCHAIN = TRUST

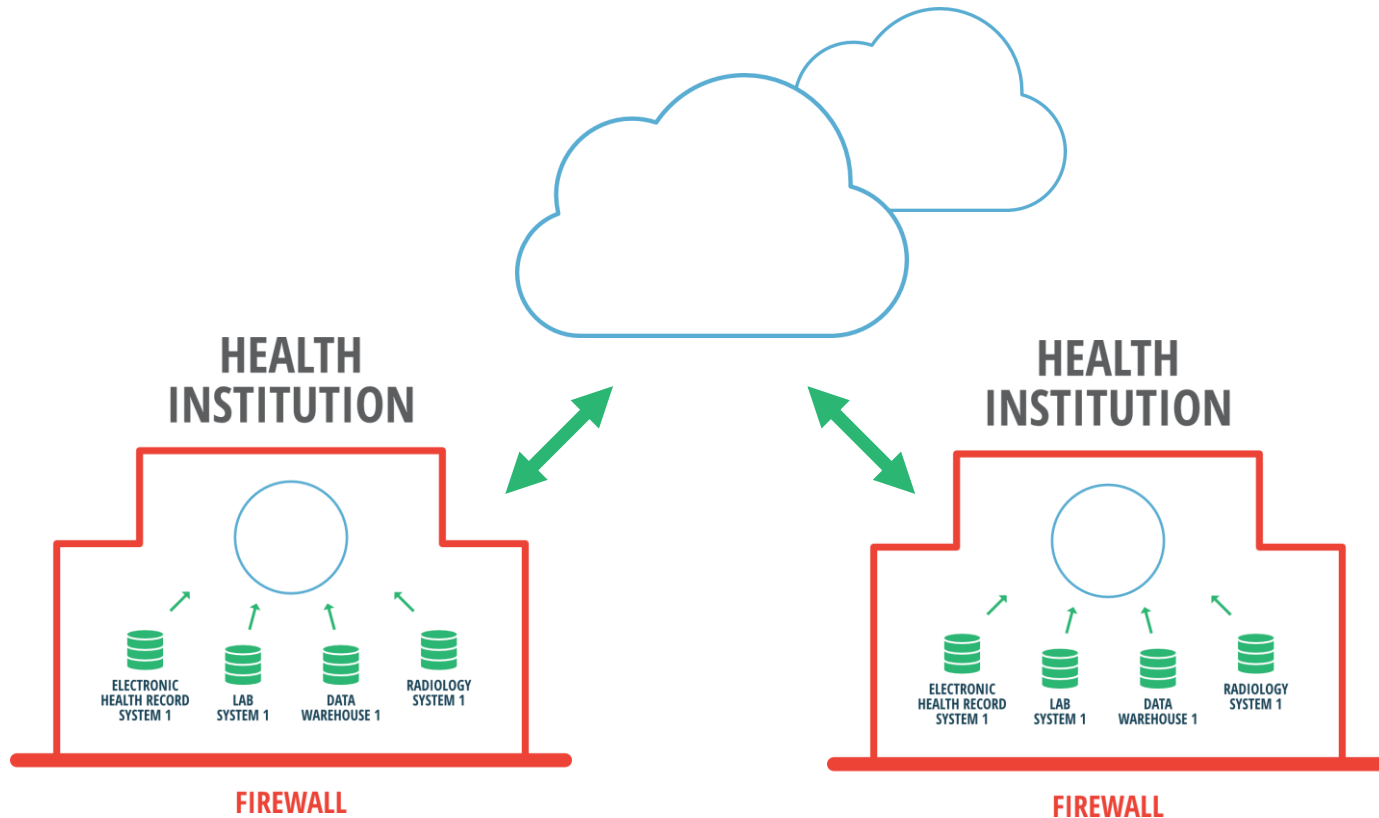


DATA ANALYTICS USE CASE



- SPECIFICALLY FOR ENTERPRISES
- BEHIND CORPORATE FIREWALL
- PERMISSIONABLE TO CONNECT WITH OTHER SYSTEMS

CONNECTED HEALTH INSTITUTIONS



Patient Experience in Pharmaceutical Clinical Trials

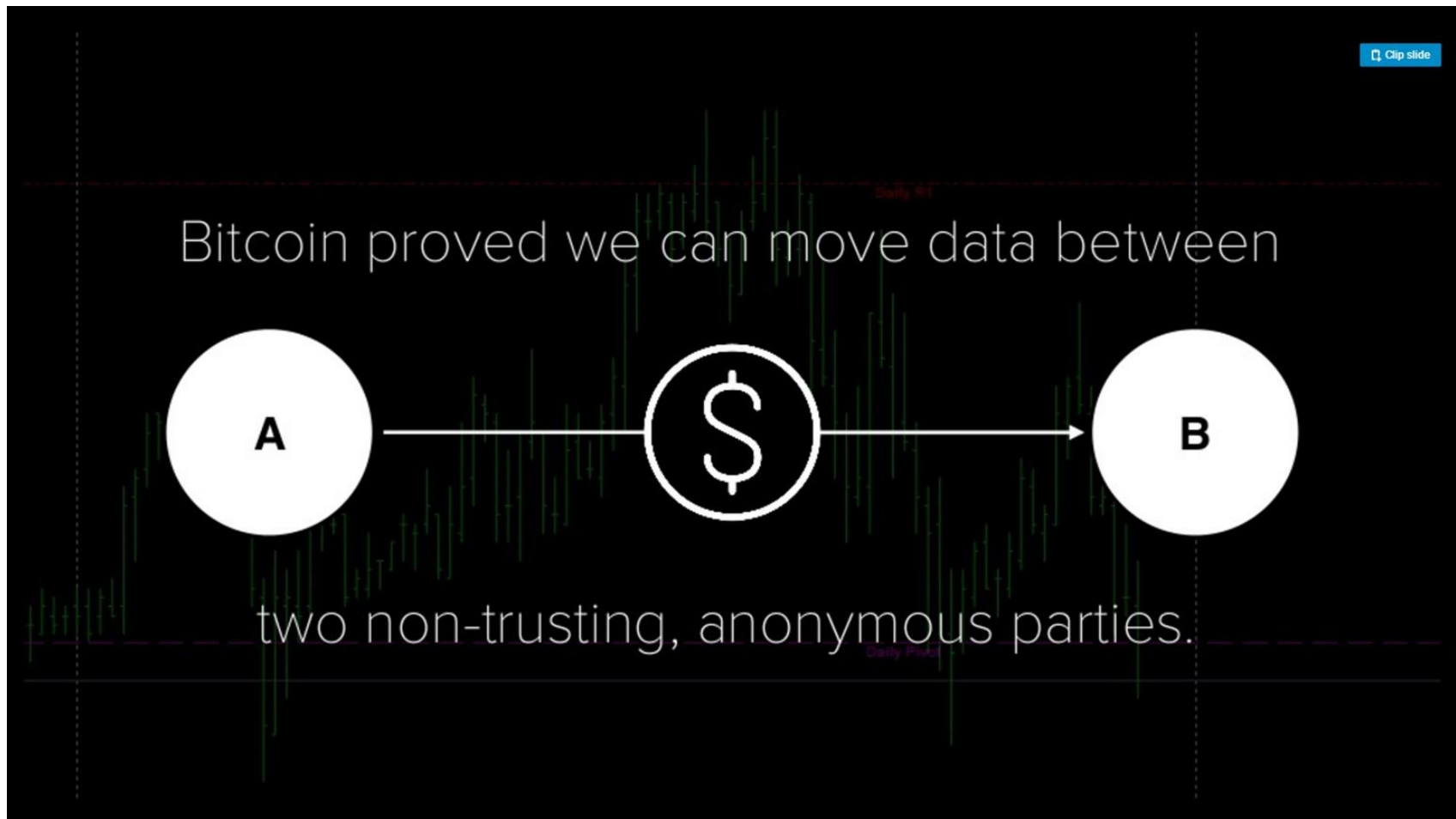
EDWARD BUKSTEL
CEO, Clinical Blockchain



Investigators are the Pharma Equivalent to Financial Intermediaries

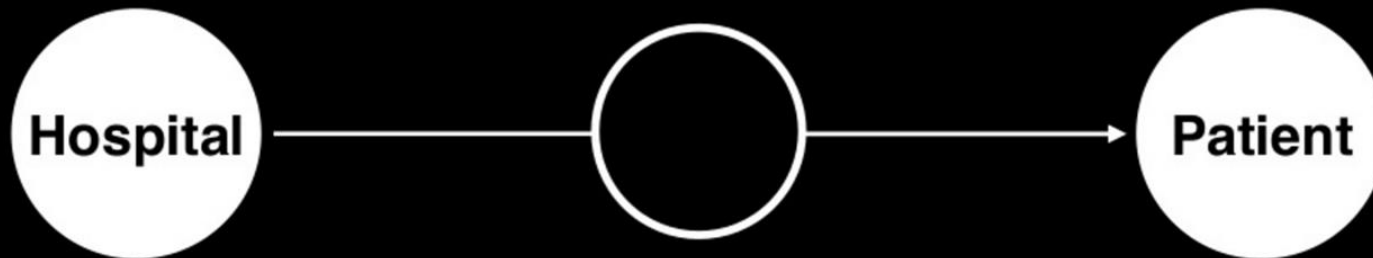


Bitcoin, Ethereum Validated Blockchain Anonymity Transactions

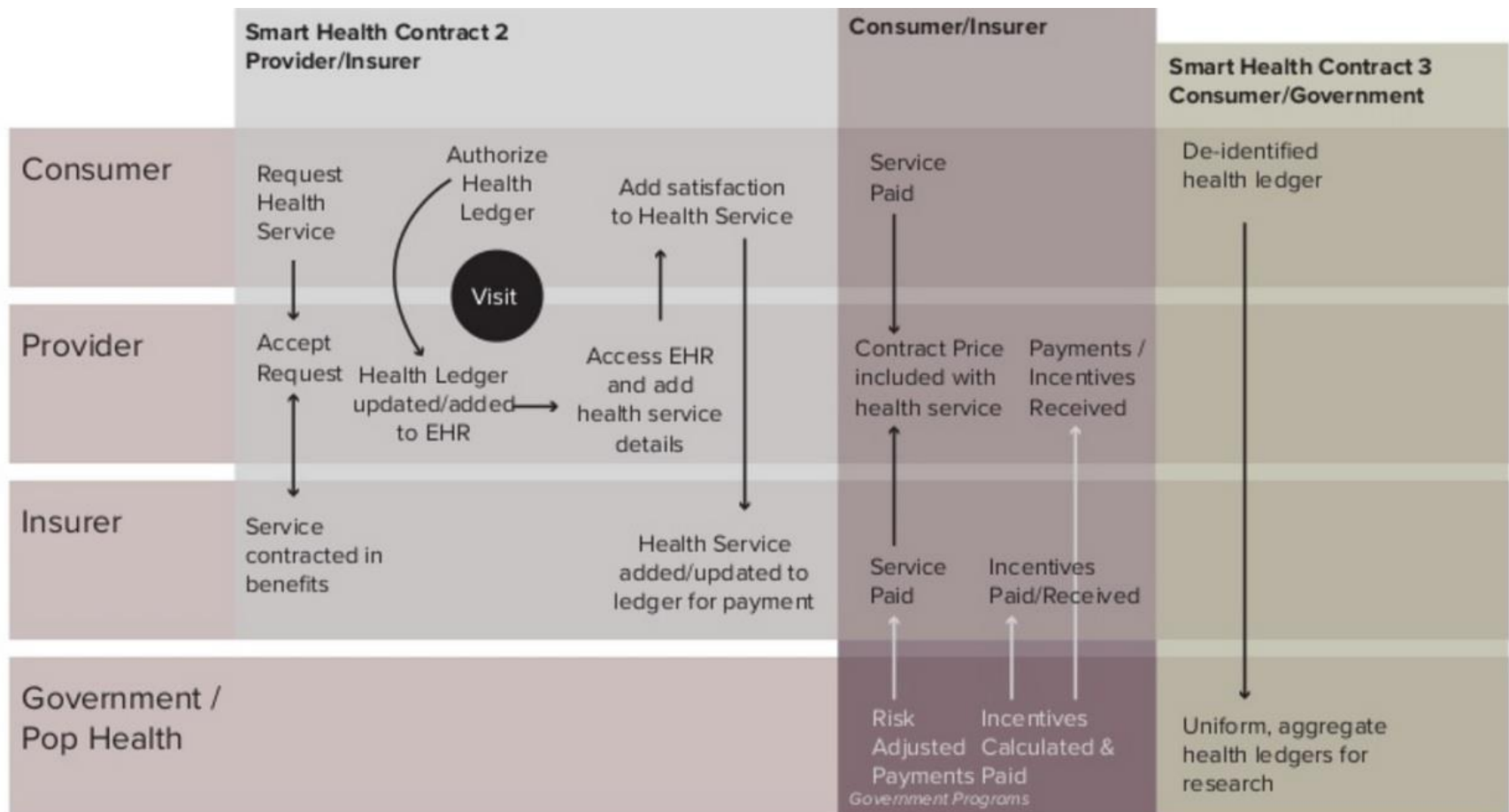


Trust in Healthcare is “Assumed”

But what if we know the other party?



Blockchain is Not a Fit for All of Healthcare



Clinical Blockchain Pharmaceutical Use Case

- Individual, personalized, and patient-centric medicine represents the future of clinical research, notably in oncology. We need to write protocols and plan recruitment strategies based upon individual patient needs and not on a disease class.
- Clinical Trials Recruitment comprises around 40% of the US pharmaceutical industry's collective clinical trial budget
- Patient-centric clinical trial recruitment only initiates a trial site once at least one interested, pre-identified patient is found.



SOCIATION

Peer-to-Peer



CLINICAL
BLOCKCHAIN



IEEE

Drug Companies Pin Hopes On TrialReach To Enroll Patients In Clinical Trials Faster



Zina Moukheiber, CONTRIBUTOR

I cover digital health, I'm also the editor of Forbes Middle East. [FULL BIO](#)

Opinions expressed by Forbes Contributors are their own.

Two years ago, Pfizer [PFE -2.69%](#), Novartis, and Eli Lilly set aside competition to form a consortium called Patients to Trials. Goal: To solve an issue that has bedeviled their industry and slowed drug development—namely how to enroll patients in clinical trials faster. According to CenterWatch, 75% of the public is unaware of clinical studies, and nearly half of trials don't fulfill their recruitment goals, causing delays. “If we can compress [From The Editor](#) | August 30, 2016



we can get medicines to patients much faster. I'm formerly vice president of Clinical In Eli Lilly, and president of Patients to

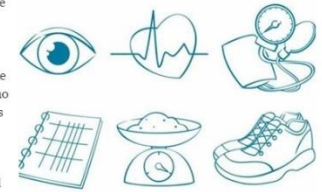
JDRF Hopes Technology Will Solve Patient Recruitment Challenge

Source: Clinical Leader

By Ed Miseta, Chief Editor, Clinical Leader
Follow Me On Twitter @EdClinical

Derek Rapp, the president and CEO of JDRF, the leading global organization funding type 1 diabetes (T1D) research, is familiar with the challenges patients face when trying to find a trial. He has one son who was diagnosed with the disease almost 12 years ago and a second son who has spent years participating in a clinical trial, as he has multiple antibodies (a precursor to the disease) and is at risk of contracting it, as well.

Rapp also cites statistics noting 80 percent of all trials are delayed due to recruitment issues. Over the next decade he expects the number of trials to increase. The primary mission of JDRF is to accelerate therapies reaching the marketplace that will help patients living with diabetes and to ultimately find a cure. Therefore, anything the organization can do to speed up trials is time well spent and a win for the group and its members.



Clinical Blockchain Use Case for Rare Disease Patients

- 33M Rare Disease Patients in US excluding Cancer.
- Health Care Providers receive significant revenue for treatment of these patients, in some case over \$1M per year.
- Rare Disease Patients have requirements relating to record security, portability, messaging and research that have not been addressed.
- Clinical Blockchain supports this unique patient group.
- Jess Jacobs example of special requirements of community.

PharmaVOICE - February 2016

[Download PDF](#) [Purchase Issue](#) [Reprint Quote](#)

Patients and Patient Organizations Power Rare Disease Therapies

Contributed by:

Robin Robinson



For most of the pharmaceutical industry, the focus on patient centricity is a relatively new phenomenon, and the industry continues to shift its focus to include patients as stakeholders when planning its marketing strategies, clinical trials, and R&D strategies.

However, for the rare disease sector, the patient has always been front and center, championing for new therapies, looking for treatments, and demanding that the industry pay attention to their unmet needs.

In fact, if it weren't for the actions of empowered patients, some rare disease treatments might not even exist. Our experts say patient networks and advocacy groups greatly influence rare disease research and development, clinical trials, regulations, and marketing efforts.



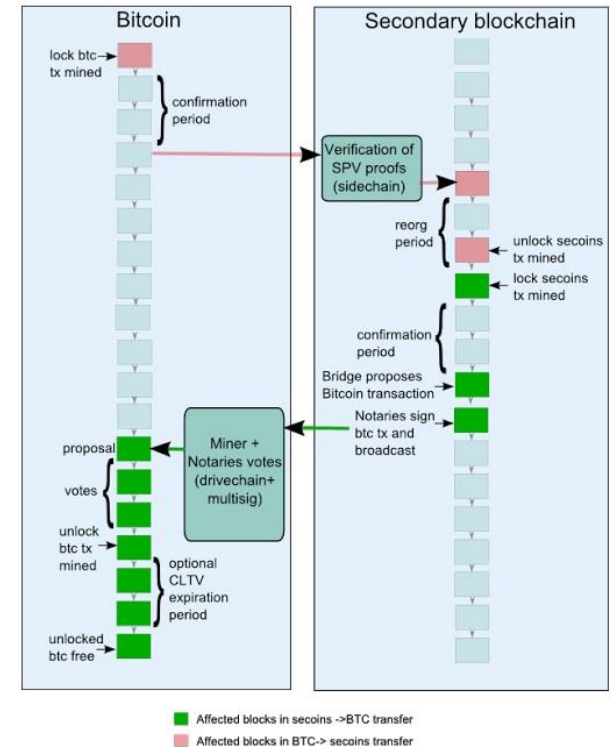
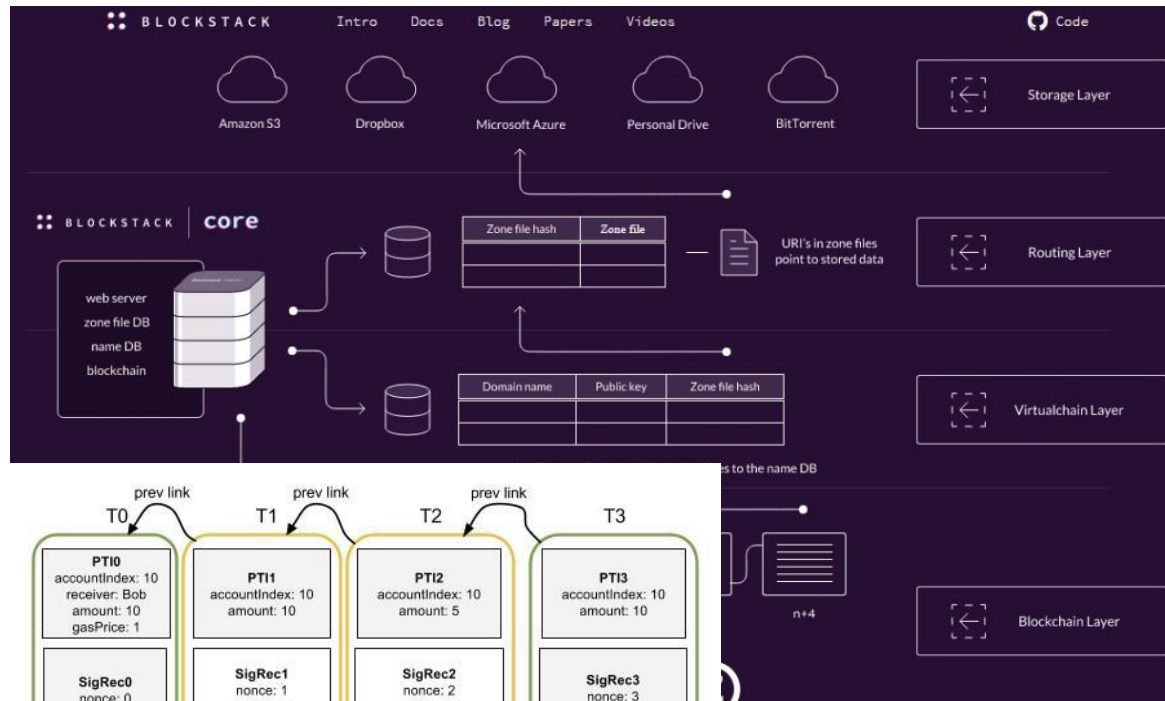
Factors impacting rare diseases and orphan brands is the



| | | |
|-----------------------------------|---------|-------|
| Date of Surgery | | |
| Type of Surgery | | |
| Institution Where You Had Surgery | name | phone |
| | address | |
| Medical Record No. | | |
| Surgeon | name | phone |

The ONLY comprehensive system for managing essential medical information.

Blockchain Innovations: Healthcare Complexity

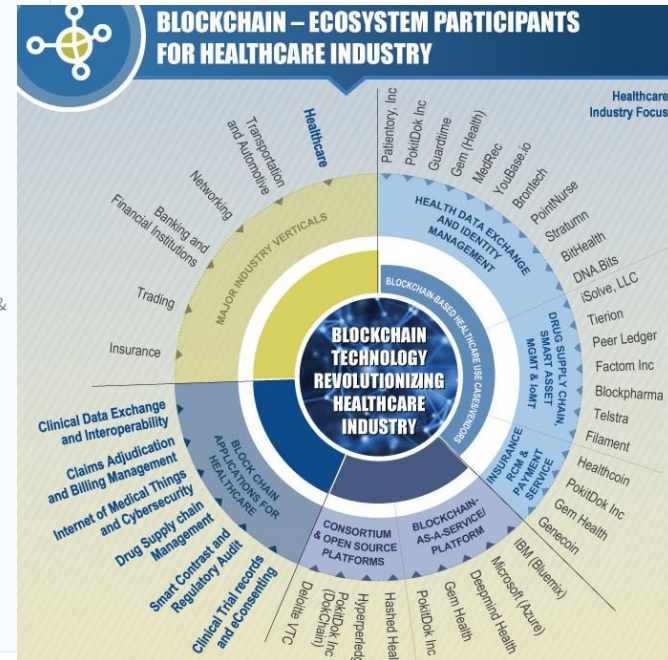
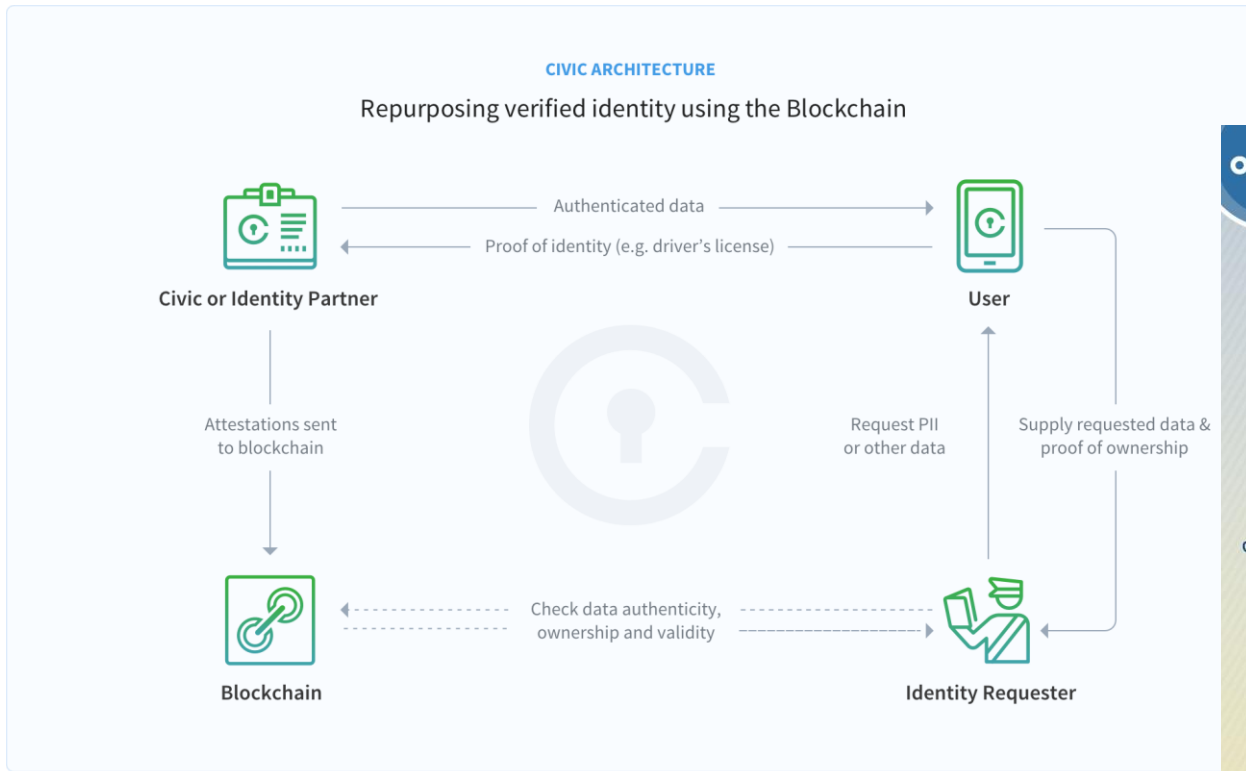


Blockstack has created a structure that is blockchain agnostic and addresses large files, such as patient data

Rootstock has created interoperability among different blockchains

Lightning provides 2000+ transactions per sec on a bitcoin blockchain

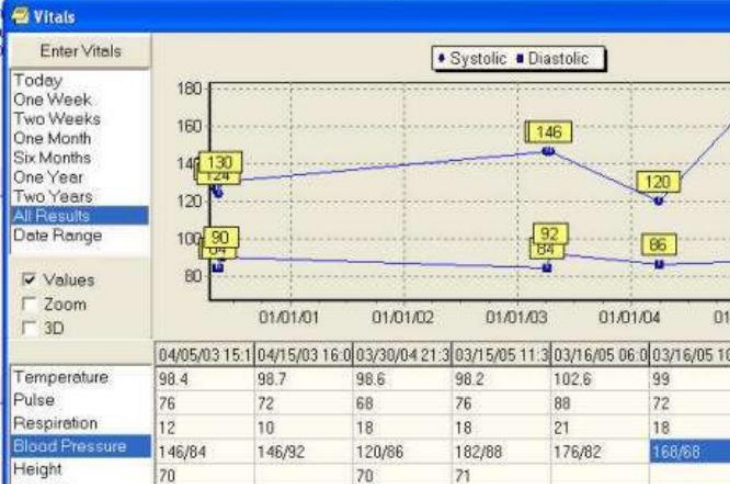
Identity: Are you a Pharma? Are you a Patient?



Time for a Healthcare Ledger

Vital Signs

From VA VistA EMR



RUN DATE: 06/19/12
RUN TIME: 1637
RUN USER: VZJ10

St. Luke's Magic Valley Reg LAB *LIVE*
801 Pole Line Road West
Twin Falls, ID 83301
Inquiry/Broadcast Report
PCI User: VZJ10 Lab Database: LAB.MYR

Name: HALKIEWICZ, JUDITH ANN DOB: 12/08/50 Attend Dr: Padavanija, Phatama
Acct#: HF039095542 Unit#: NR00507837 Age/Sex: 61/F Location: HF.CC
Reg#: 06/19/12 Blatch Status: RND RCR

Spec #: 0619:NR03108 Coll: 06/19/12 1602 Status: RES Reg #: 02562014
Recd: 06/19/12 1609 Subm Dr: Padavanija, Phatama
Salm Dr: Phone#: 208-814-1600
Othr Dr: Area, Out of

Ordered: CBC MORPHOLOGY, CBC TREAT

| Test | Result | Flag | Reference |
|-----------------|--------|------|----------------------|
| CBC TREAT | | | |
| WBC | 4.5 | | 4.5-11.0 K/UL (RNR) |
| HGB | 4.08 | | 3.5-5.5 M/DL (RNR) |
| HCT | 13.2 | | 12.0-15.0 G/DL (RNR) |
| MCV | 39.7 | | 36.0-48.0 fL (RNR) |
| MCH | 97.2 | | 79.0-101.0 fL (RNR) |
| MCHC | 32.4 | | 28.0-38.0 g/dL (RNR) |
| RDW-CV | 18.0 | | 11.0-14.0 % (RNR) |
| PLT | 298 | | 140-440 K/UL (RNR) |
| MPV | 6.7 | | 7.0-10.0 fL (RNR) |
| NEUT % (AUTO) | 61 | | 40-76 % (RNR) |
| LYMPH % (AUTO) | 25 | | 24-44 % (RNR) |
| MONO % (AUTO) | 10 | | 1.0-10.0 % (RNR) |
| EOS % (AUTO) | 2 | | 0.0-5.0 % (RNR) |
| RBCO % (AUTO) | 2 | | 0-1 % (RNR) |
| NEUT AB (AUTO) | 2.71 | | 1.9-8.8 K/UL (RNR) |
| LYMPH AB (AUTO) | 1.11 | | 1.0-4.8 K/UL (RNR) |
| MONO AB (AUTO) | 0.43 | | 0.1-0.8 K/UL (RNR) |
| EOS AB (AUTO) | 0.12 | | 0.0-0.5 K/UL (RNR) |
| RBCO AB (AUTO) | 0.08 | | 0.0-0.1 K/UL (RNR) |

```
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<Observation>
<id value="observation-1"/>
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<system value="http://loinc.org"/>
<code value="1554-5"/>
<display value="GLUCOSE/POST 12H CFST:MCNC:PT:SER/PLAS:QN"/>
</coding>
</code>
<valueQuantity>
<value value="182"/>
<units value="mg/dL"/>
<system value="http://unitsofmeasure.org"/>
<code value="mg/dL"/>
</valueQuantity>
<interpretation>
<coding>
<system value="http://hl7.org/fhir/v2/0078"/>
<code value="N"/>
</coding>
</interpretation>
</valueQuantity>
</code>
</Observation>
</contained>
</DiagnosticReport>
</resource>
```

9:30 58%

Patient: Sammy Smith
DOB: March 20, 1975
Cell: 215-767-5555

Walgreens AT THE CORNER OF HAPPY & HEALTHY

Balance Rewards Weekly Ad & Coupons Store Locator Healthcare Clinic

Pharmacy Prescription Refills Health Info & Services Contact Lenses Shop Products Photo

Search by keyword or item #

Your Health Dashboard

Johnny Flu... Julie Flu...

Prescriptions

| Prescription(s) (7) | Refills Left | Last Filled |
|-------------------------------|--------------|-------------|
| IBUPROFEN 100MG/5ML ORAL SUSP | 0 | 01/21/2015 |
| IBUPROFEN 100MG/5ML ORAL SUSP | 0 | 09/19/2014 |
| FLAVOR SWEET SYRUP | 5 | 09/19/2014 |

Full prescription view Already placed an order? View Rx status Request refill(s)

Side Effects patientslikeme

Gabapentin

Patients reported:

- Weight gain 10%
- Fatigue 5%
- Sleepiness 5%
- Drowsiness 1%
- Dizziness 5%



Scan Medical Records
Text Message Doctors



Questions?

IEEE Blockchain Initiatives & Activities

INITIATIVES

- Supply Chain/Clinical Trials Technology Implementation Industry Connections Program – **NEW**
- Digital Inclusion through Trust and Agency Industry Connections Program –
<http://bit.ly/IEEEDigitalIdentity>



Blockchain Special Interest Group (SIG) on SLACK

<https://blockchain-ieee.signup.team>

ACTIVITIES

- **IEEE-SA's *State of Blockchain Adoption on the Pharma Supply Chain Research Study*** available for purchase week of 23 Oct 2017
- **Cutting to the Trace with Blockchain Workshop**
8 November 2017 – Washington, DC
presented at the HDA (Healthcare Distribution Alliance) 8th Annual Traceability Seminar
- IEEE Blockchain Hosted Session at **7th Annual CROWN Congress**
25 January 2018 in Philadelphia
- **Blockchain 4 Clinical Trials Forum**
12 February 2018 – Orlando, FL



Blockchain.ieee.org

THANK YOU FOR PARTICIPATING

<http://blockchain.ieee.org>

If you are interested in IEEE
Blockchain activities, write to
m.palombini@ieee.org.

