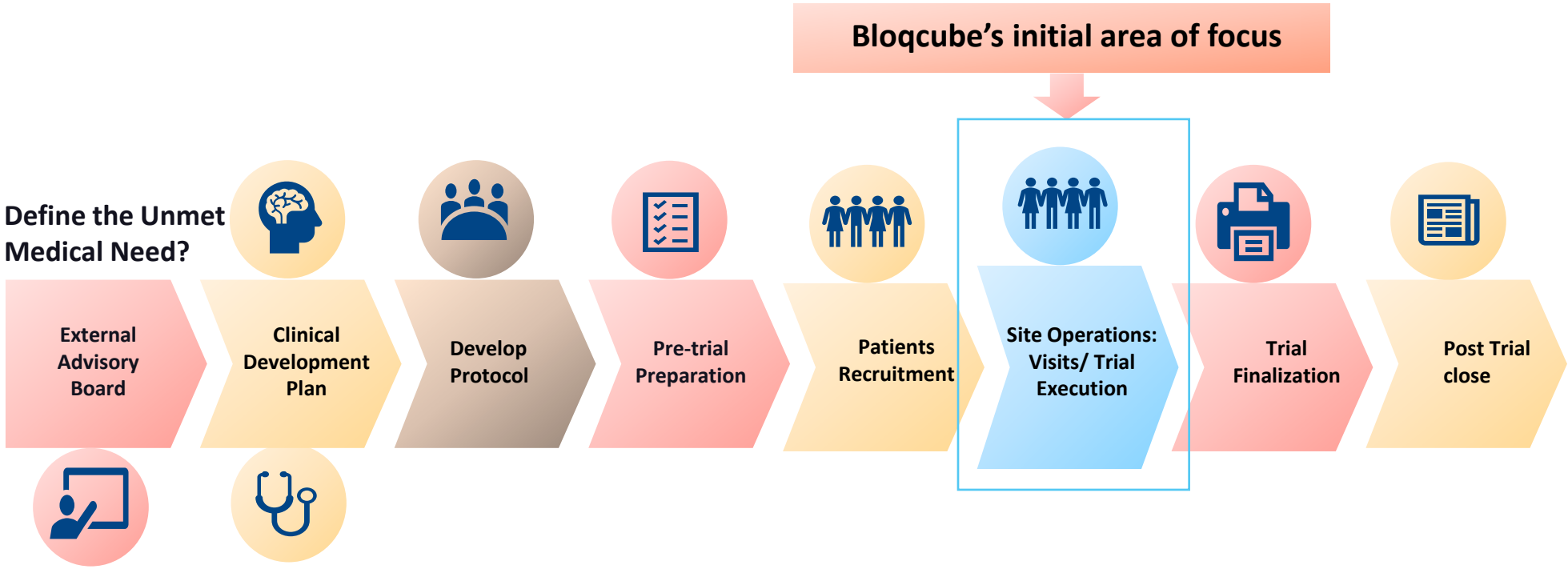
Bloqcube®: B2B Clinical Trials Software Platform for Accelerating Clinical Trials

Clinical trials by Pharma companies are costly, inefficient, time consuming with multiple systems used



Problem: Operational inefficiencies clinical trials

Covid has propelled digital adoptions and shift to patients' homes (Decentralized Clinical Trials –DCT)

Operational inefficiencies by the move to DCT

Lack of Realtime data and multiple systems

Data Integrity challenges

Regulatory guidelines require manual monitoring

Payments' Delays to patients and sites

4 months delays and 41% churn

Pain points: 85% of all trials delayed; costs up to $8m/day

The industry is moving currently at a more rapid pace to digitalization of trials post Covid

Trials moving to Patients' homes

- Decentralized Trials (DCT) – trials in patient homes - are a new strategic reality post Covid
- Growth in this area was over **90%** 2022 vs 2020
- Current workflows with existing systems are inefficient (**~6** systems used/trial)
- FDA has issued DRAFT guidelines for DCT de-risking Regulatory risk

Data Integrity

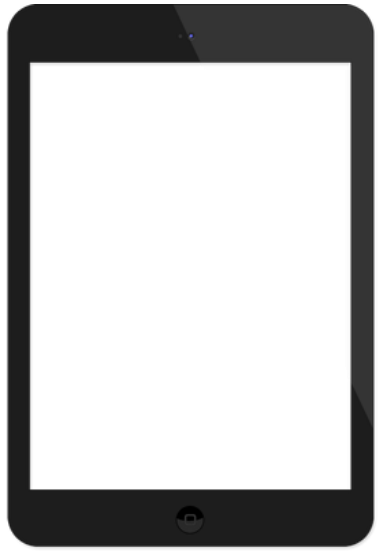
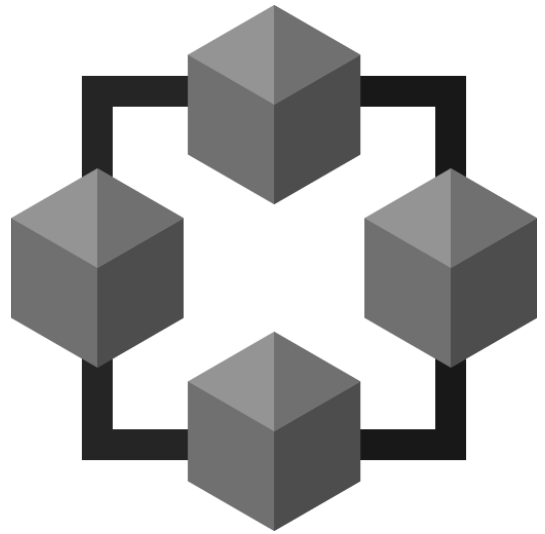
- Upto 17% data integrity issues observed (1)
- May '22: EU delisted 100 drugs due to integrity issues in one firm(2)
- Even Big Pharma was accused by FDA of data manipulation for a $2.1m drug (3)

Financial settlements

- Sites/Doctors get paid late ~4 months
- Resulting in 41% churn in sites participation
- Causing disconnects in resources management, and high transaction costs (~$1B) for financial payments

Solution: A blockchain enabled e-clinical software

Intuitive and ease to use in diverse target segments; unlike Medable or Science 37 we offer an additional Finance+SCM module and lesser vulnerability due to Ransomware attacks

iPad /Smart Phone	Cloud / Decentralized	**Blockchain enabled**
		

21CFR Part 11 compliant

Solution: A blockchain enabled e-clinical software

Intuitive and ease to use in wide target segments

iPad /Smart Phone

- Data collected electronically at the source or patients' locations
- Multiple systems integrated in a modular fashion decreasing data integrity issues
- Data quality at source
- Near future fully web based and BYOD

Cloud / Decentralized

- Data collected irrespective where patients are located geographically worldwide
- Facilitates diversity and underrepresented groups participation to comply with new regulatory guidelines

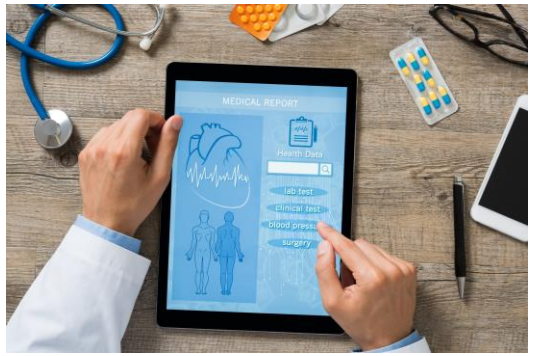
Blockchain enabled

- Immutable data collected
- One source of truth of all data for all parties
- Immutable with data integrity
- Smart contract driven integration of unique financial module-payments/accounts/budgeting

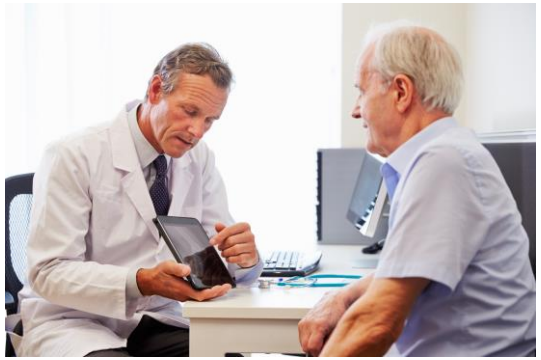
How does it work? User Personae

Lifescience product owner: Concerned that cumbersome inefficient processes delaying productivity

Site admin: Multi system paper processes for Regulatory binders



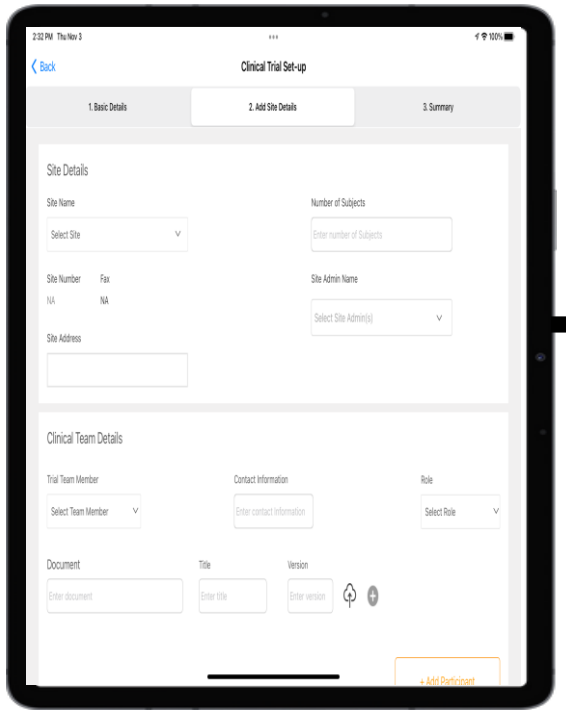
Physician/Study coordinator: Concerned about regulatory compliance and study delivery and getting paid late



Monitors/QA/Safety Boards: Supervise study check for auditability and Regulatory compliance

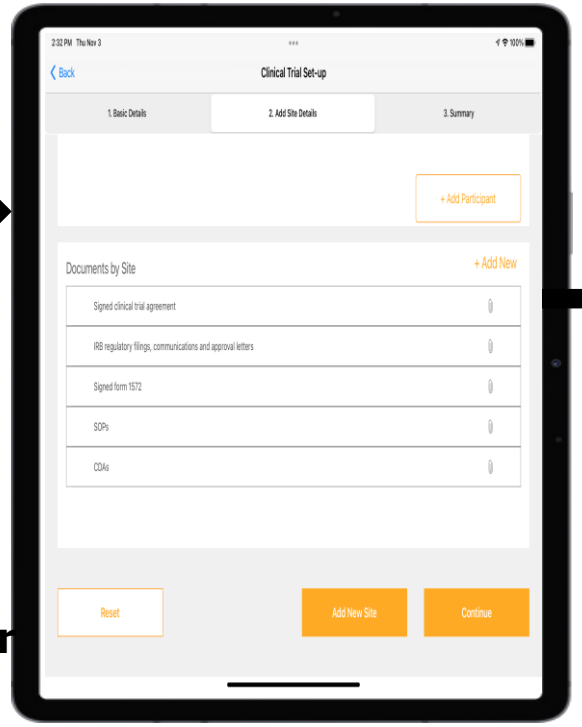
How does it work? Users' journey

Trial setup



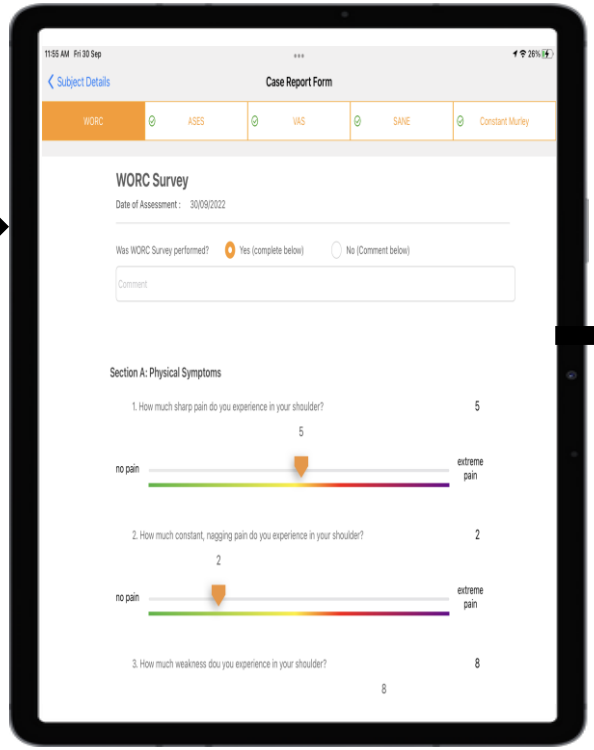
Lifescience product owner

Regulatory binders/site checks



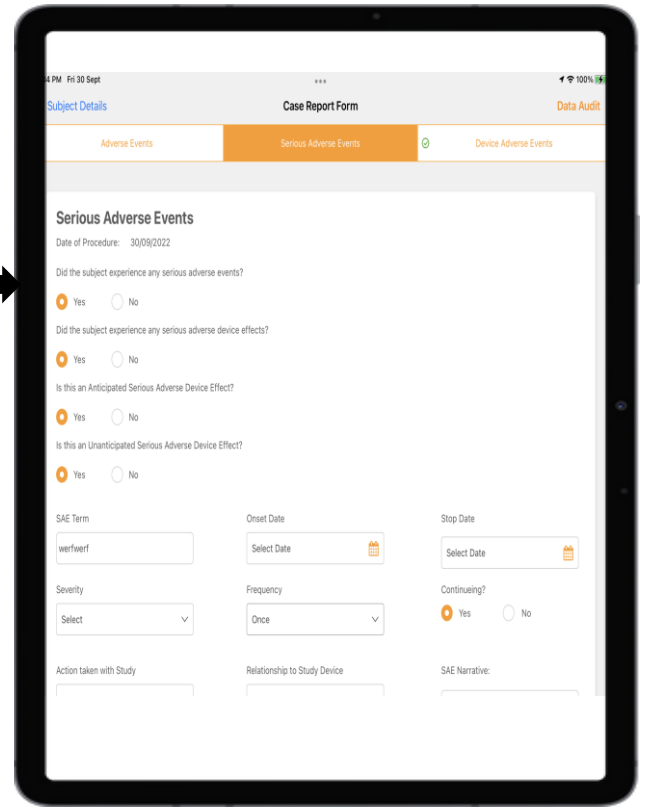
Site admin

Direct Data Capture



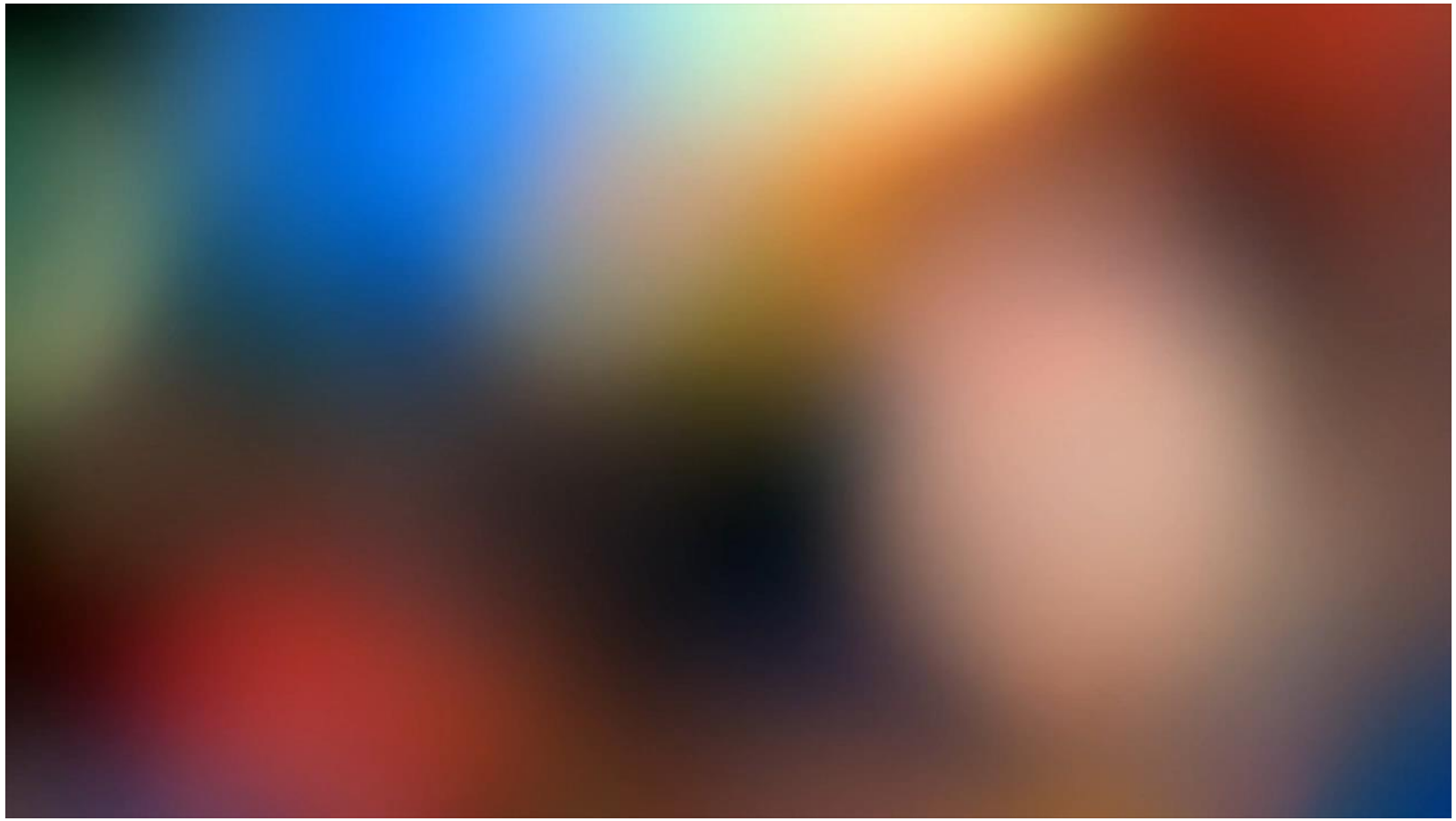
Physician Investigator
Study coordinator

Real time safety signals

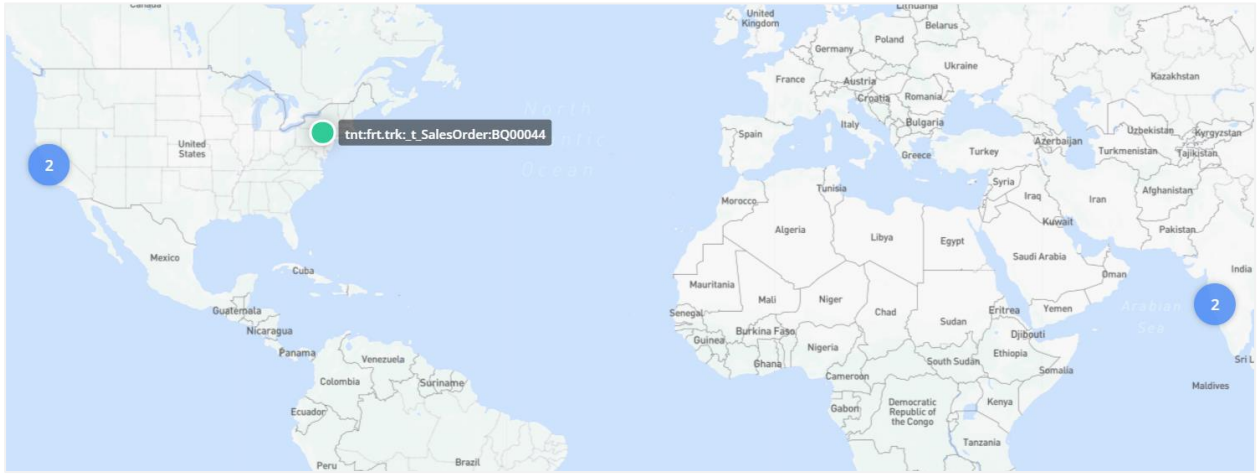


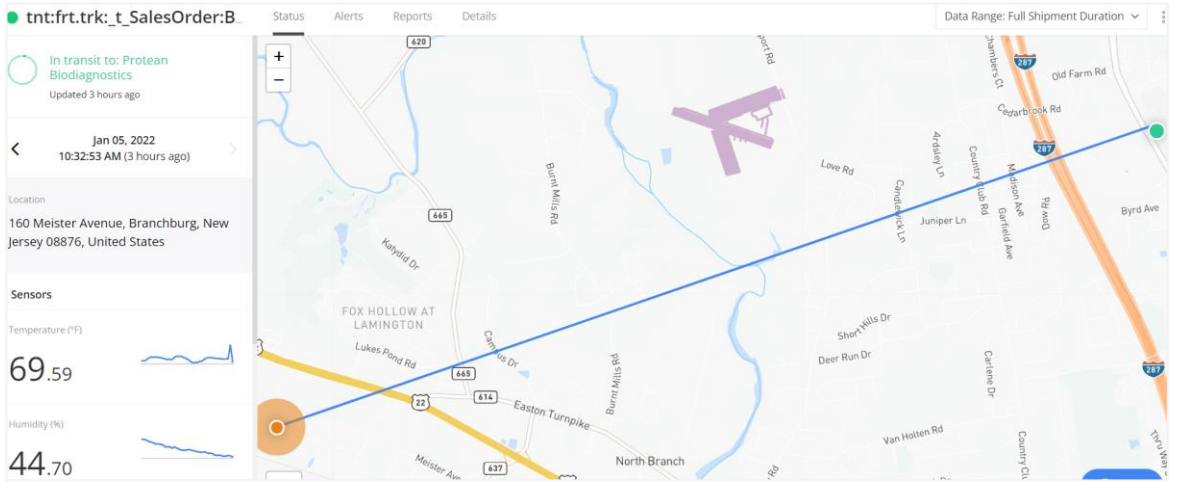
Monitors/QA/Safety Boards:

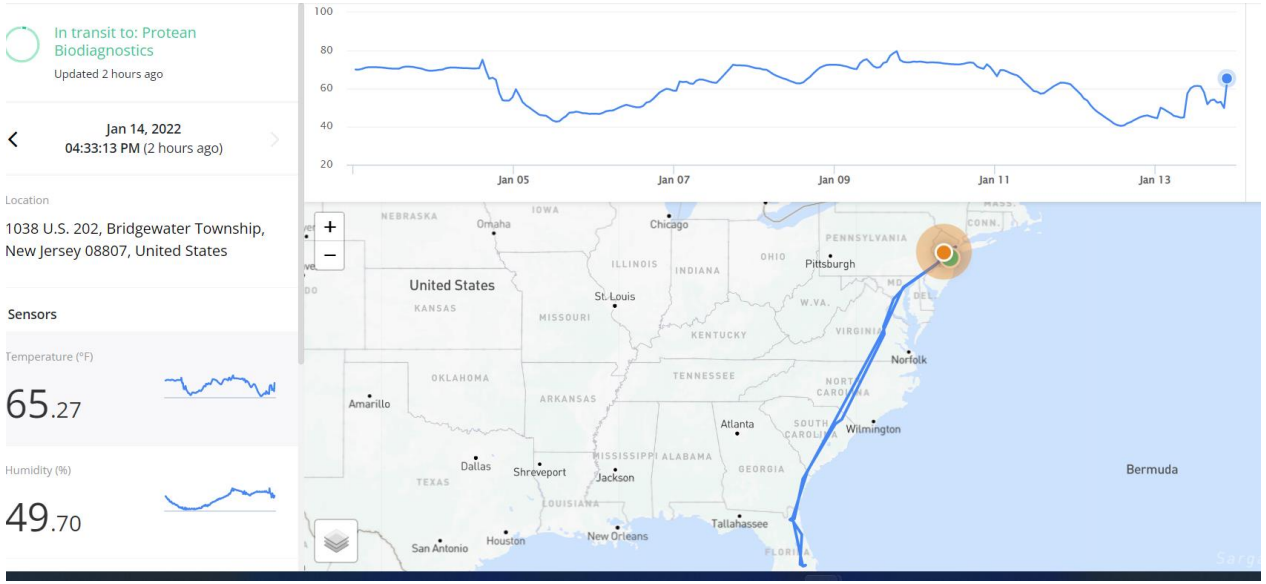
System demonstration



BloqBridge: Real time SCM transparency for trial IMP to address 50% wastage







Geo tagged

IoT controlled

Last mile delivery

https://platform.tive.com/sh/DBCE59CE0A/status/-?fullDuration&sensor=temperature

Apps | Using Google OAU... | Home - Hyperledge... | Procurement Austr... | Blockchain network... | Snap! Raise • Fundr... | Contact-us | Sigfox | Google Drive - Acc... | Reading list

tive | Shipments | Trackers | Configure | Order Trackers | Search | AJ

tnt:frt.trk:_t_SalesOrder:B... | Status | Alerts | Reports | Details | Data Range: Full Shipment Duration

In transit to: Protean Biodiagnostics

Updated 3 hours ago

Jan 06, 2022
03:35:17 PM (3 hours ago)

Location

4901 Pulaski Highway, Baltimore, Maryland 21224, United States

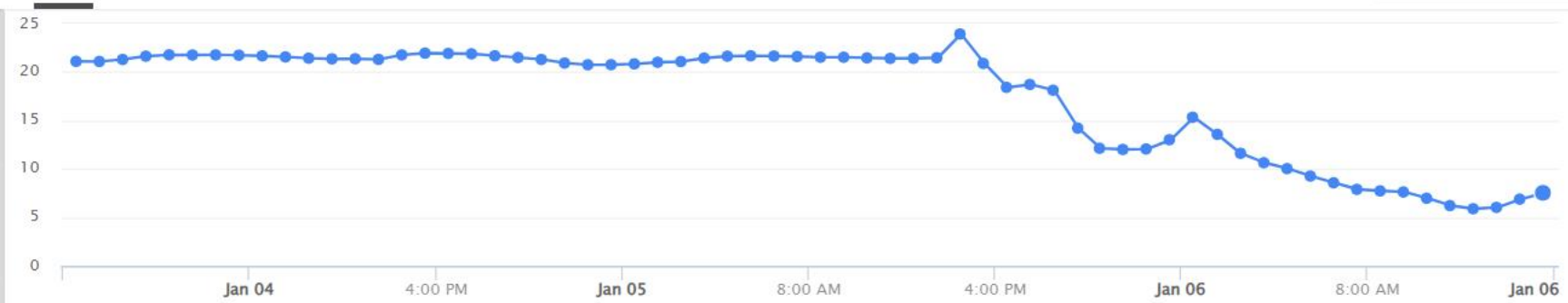
Sensors

Temperature (°C)

7.52

Humidity (%)

44.60

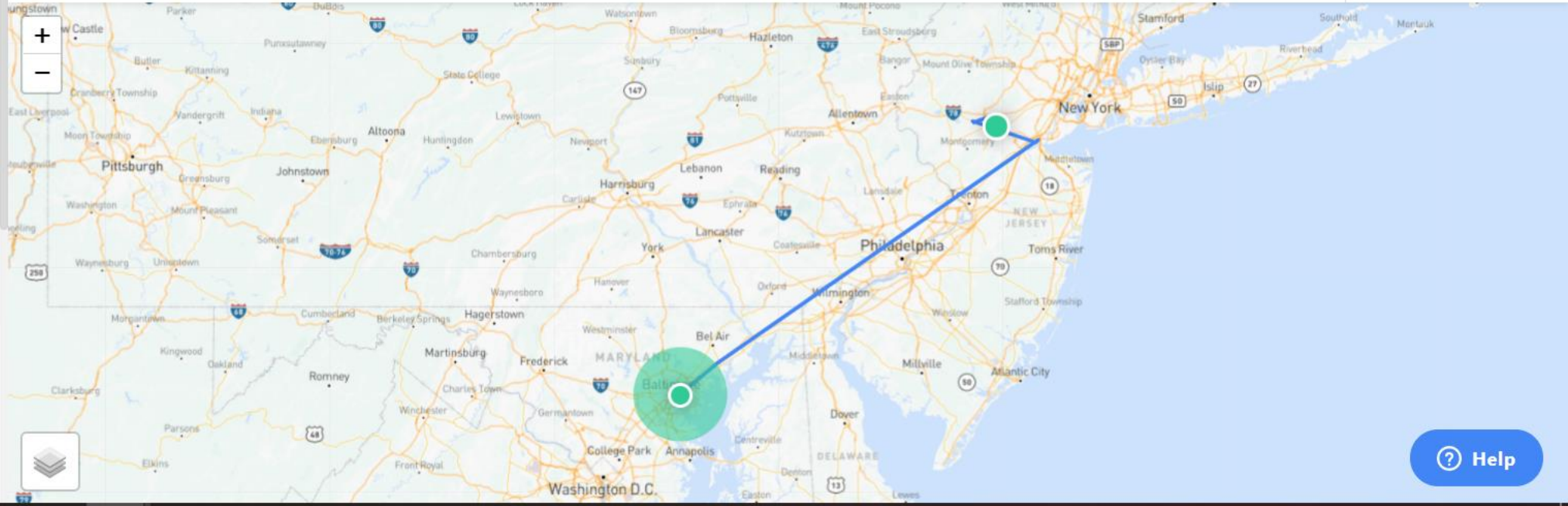


Temperature

21.09°C

Jan 04, 12:32 AM
3 days ago

MIN	AVG	MAX
5.9	17.0	23.9



Help

55°F 10:19 AM 1/6/2022

Manage

Administrator

Louis, MO 63141

Print Packing List

Master Ship List

Print QR Code

Order QR Code

Subject Name	Site Name	Site Monitor	Batch ID	Delivery status
Laura McDermott	St Bernard Hospital	Christian Watts	ACR-3457653-12	Completed

Order Details | Order Tracking | Invoices | Documents | Smart Contracts | Messages

Inspect & Pack — Pickup & Ship — In-Transit — Receive/Accept — PoS Sales — Customer Verifies

Protocol #	Protocol #	Carrrier Id	Store Id		
C4591001	C4591001	SHP-12345	STR-12345	N/A	N/A
Study Intervention #	Study Intervention #	Ship Date	Customer		
PF-07302048	PF-07302048	1/29/2021	Nordstrom		
BRIDGE ID	BRIDGE ID	Status	Location		
B-9766543	B-9766543	In-Transit to location	Dublin		
US IND #	US IND #	Batch Id	Batch ID		
19736	19736	ACR-3457653-1	ACR-3457653-1		
EduraCT #	EduraCT #	Product Status	Stock Scan Status		
2020-002641-42	2020-002641-42	Ok	QTY Mismatch		
Approved Date	Approved Date	Status	Receiving Date		
06/04/2021	06/04/2021	On time	1/29/2021		
Inspected By	Inspected By	Estimated Arrival	Received by		
Tom Harding	Tom Harding	05/6/2021	Fremont WHS		
Verify	Verify	Verify	Verify	Verify	Verify

Dashboard
Track & Trace
Manage
Administrator

IMPs Details

BRIDGE ID	Subject ID	Location	QTY	Product Status
P-767758	P-123453	615 S New Ballas Rd, St. Louis, MO 63141	30	Rejected !

Subject Name	Site Name	Site Monitor	Batch ID	Delivery status
Laura McDermott	St Bernard Hospital	Christian Watts	ACR-3457653-12	Completed

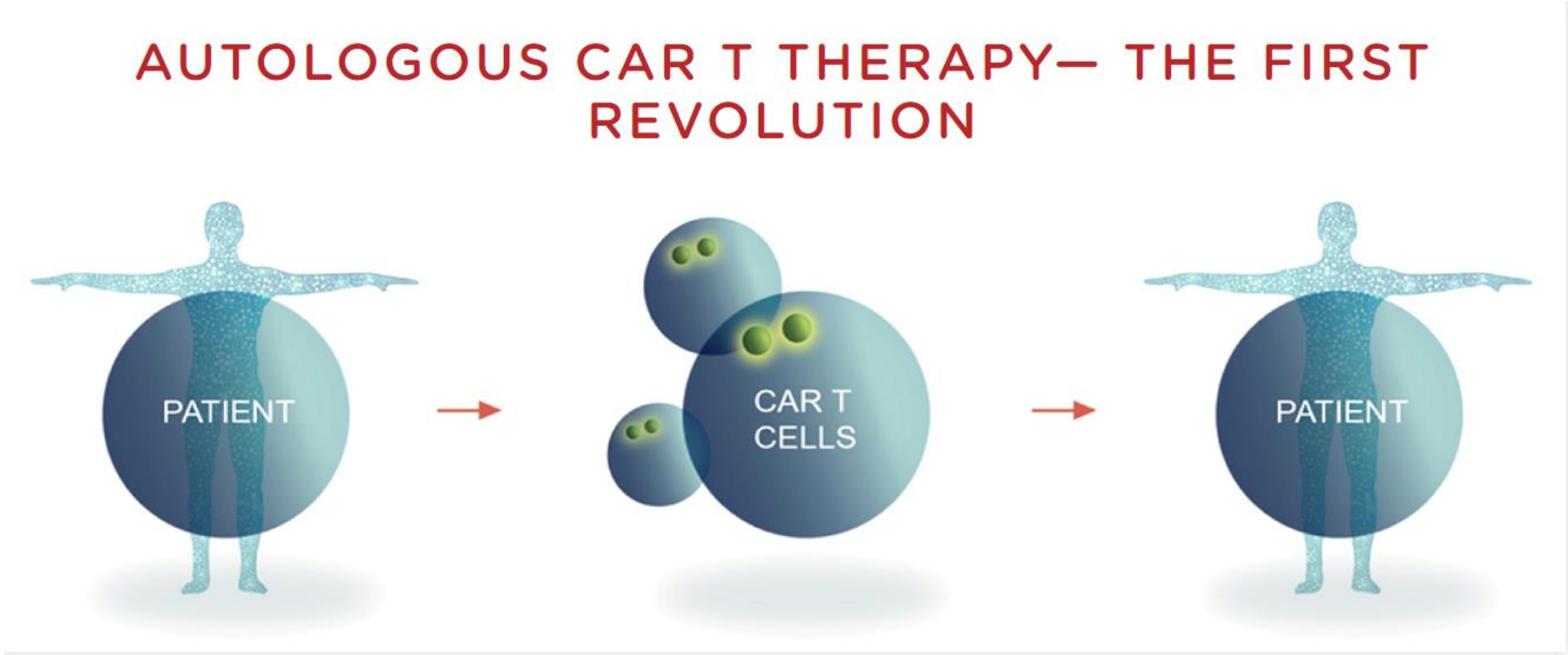
Print Order Details
Print Packing List
Master Ship List
Print QR Code

Order QR Code

Order Details | Order Tracking | Invoices | Documents | Smart Contracts | Messages

SKU	Protocol #	Batch ID	QTY
0612-009-T	GS-US-337-0131	ACR-3457653-12	30

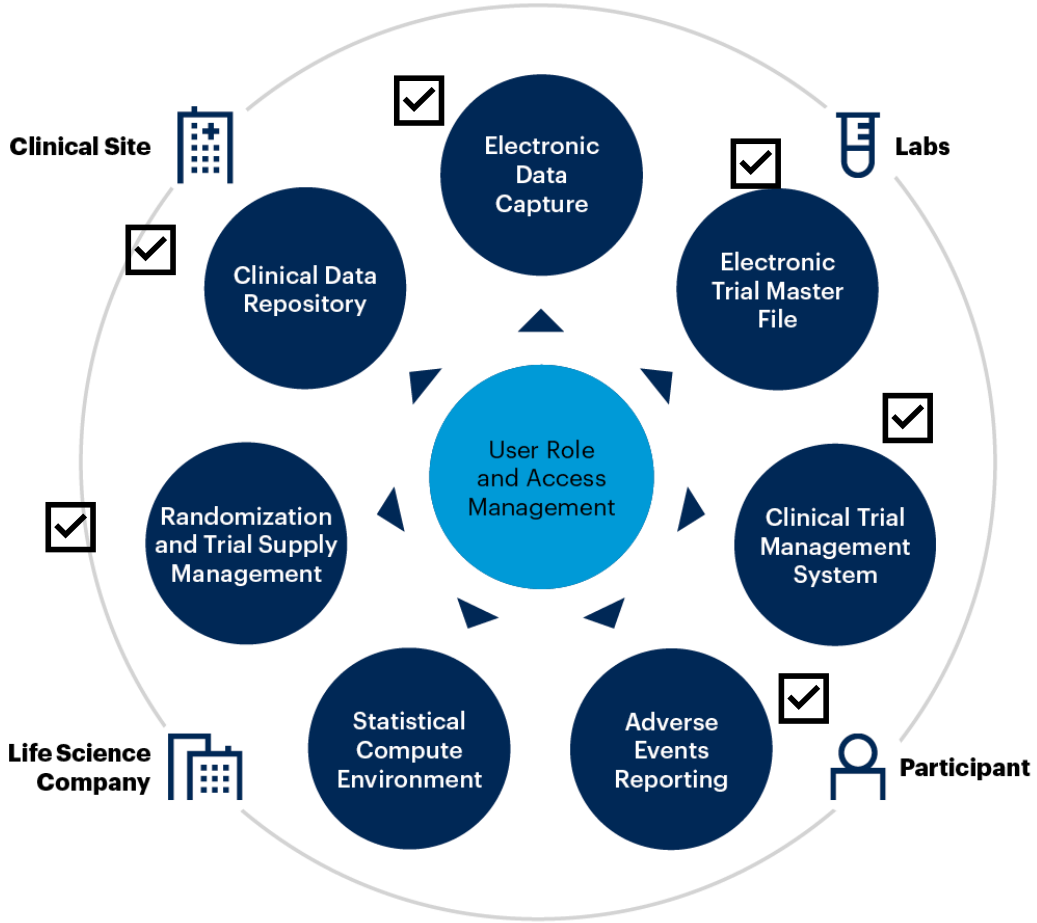
CAR-T Therapy: Another application for BloqBridge to transmit SCM data



Source: Website of Allogene Therapeutics

Unified System aligned with Best in Class global systems

E-Clinical Platforms



Financial Module C2TA™

Source: Gartner
738627_C

Gartner

Competitive Differentiation validated: CB Insights and Prix Galien

CBINSIGHTS

- Where does Bloqcube win versus:

Competitor	Attribute
MEDABLE	“Technological Lead”
Science 37	“Technological Lead”
medidata	“Pricing/Costs”

Source: https://www.cbinsights.com/company/bloqcube/alternatives-competitors

- "The Prix Galien Awards have become the most coveted prizes for those who dedicate their lives to the development of meaningful drugs and innovations," said Bernard Poussot, Director, Roche Holding, Former Chairman & CEO, Wyeth, *Prix Galien Startup, Digital Health and Incubators, Accelerators and Equity Committee Chairman*”.
- **Bloqcube® has been nominated as a Prix Galien Startup in the Digital Health category (one of only 13)**

Source: https://www.prnewswire.com/news-releases/the-galien-foundation-announces-2022-prix-galien-usa-nominees-for-best-digital-health-solution-incubators-accelerators-and-equity-and-prix-galien-startup-301595188.html

Competitive advantage and moat driven by our domain expertise

Competition

We are nicely poised to win this game

	BLOQCUBE	ORACLE IBM	Science 37	MEDABLE	Veeva	BIOCLINICA	greenphire	medidata
Fully Decentralized	●	○	●	●	●	○	○	○
Digital Dollar/ CBDC ready	●	○	○	○	○	○	○	○
Pay, Accounting export *	●	○	○	○	○	●	●	○
SCM	●	○	○	○	○	○	○	○
Real Time	●	○	●	●	○	○	○	○
eCOA	●	●	●	●	●	●	○	●
EDC/ CTMS	●	●	●	●	●	●	○	●

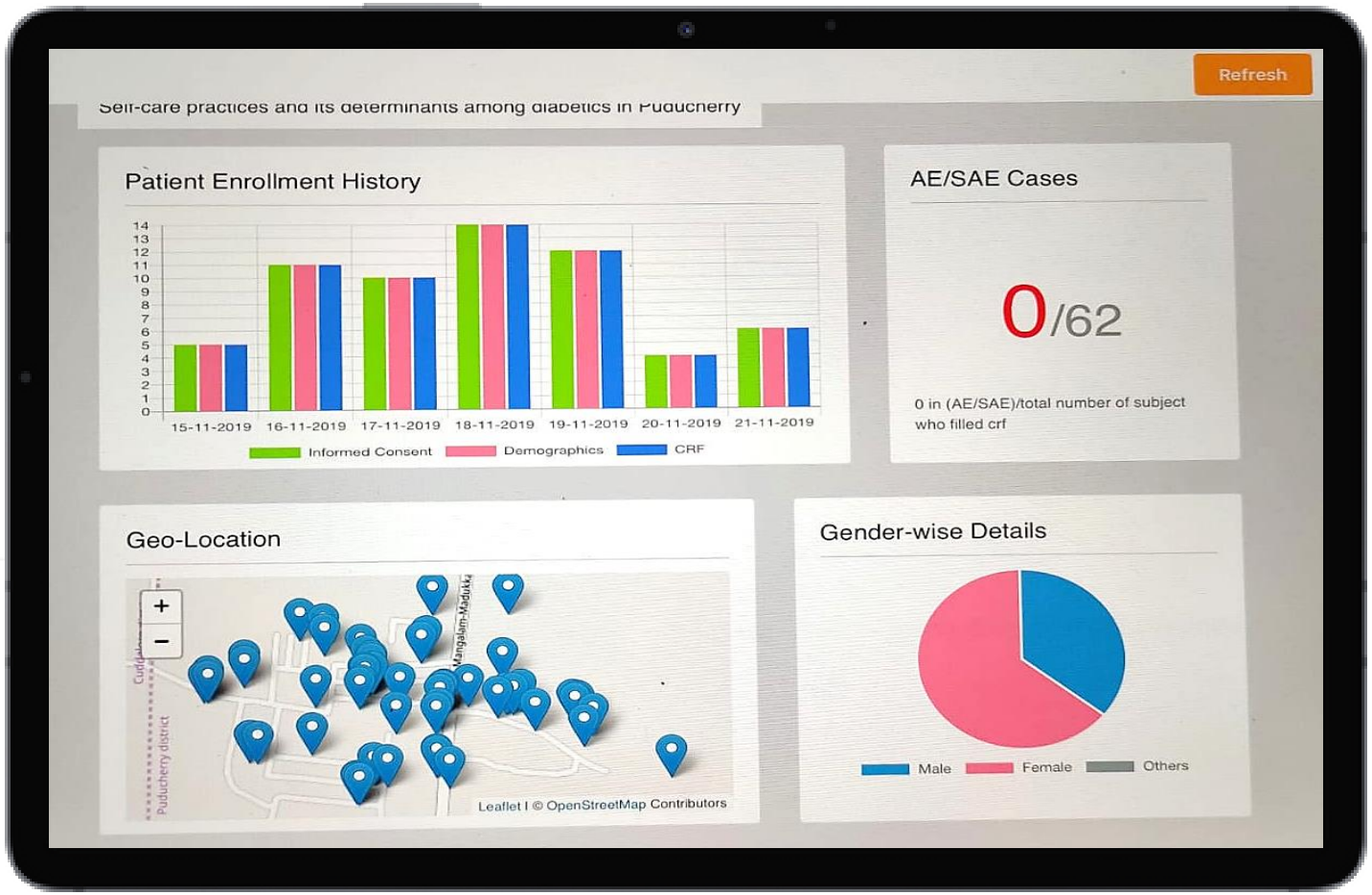
Competitive Landscape:

* Patent pending (C2TA™)

*Source: Veeva study indicates 99% dissatisfaction with existing systems; https://www.veeva.com/resources/industry-survey-shows-87-of-clinical-operations-leaders-taking-action-to-unify-clinical-processes/

Customer 1: a 50% decrease in time*

BLOQCUBE
SMART.SECURE.SPEEDY

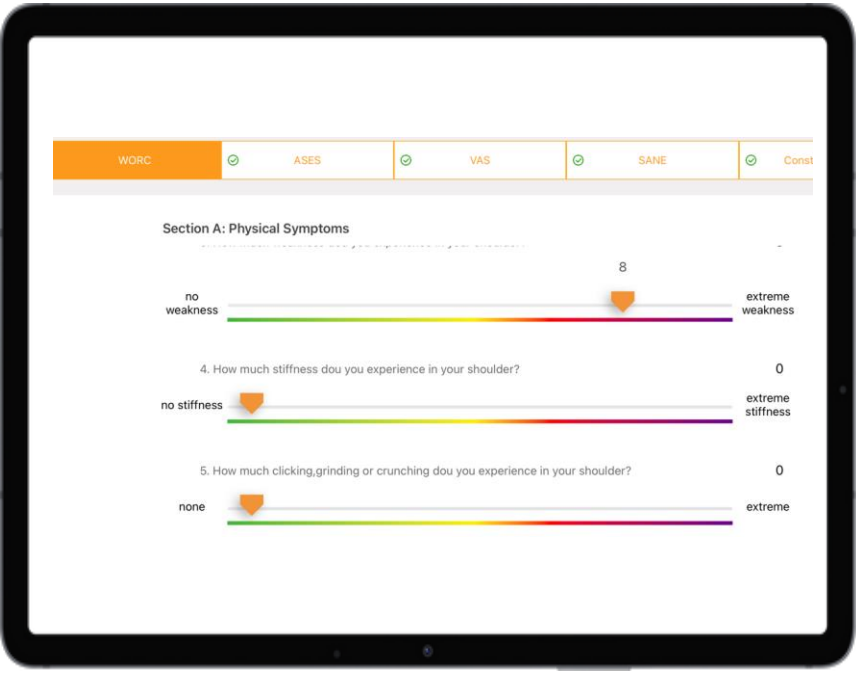


- Multiple modules shown in clip below:
- https://bloqcube.com/bloqcube-system-video/

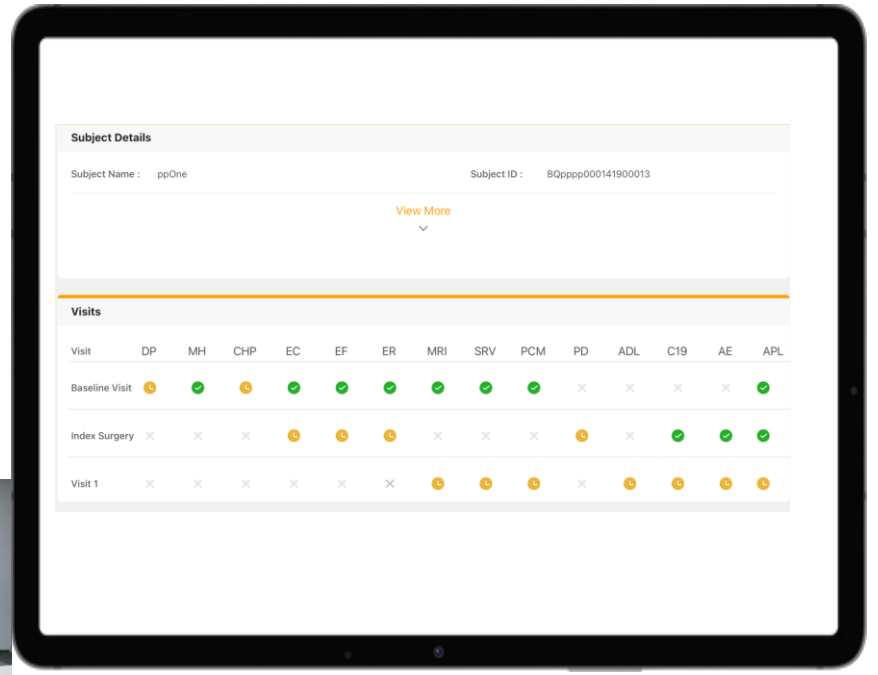
*: Observational Diabetes study conducted by Indira Gandhi Medical College and Hospital, Puducherry

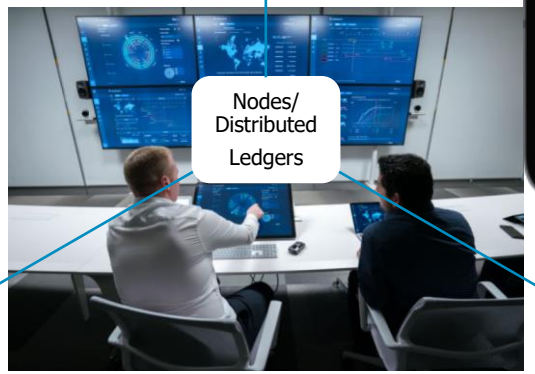
Customer 2 : 65 people screened in 6 hours*

Customer 3: Decentralized clinical trial platform handed to client in Q1*



Site in Asia Pacific





Nodes/ Distributed Ledgers

Biotech firm in NE US

CRO in SW US

* Under CDA

Customer Feedback

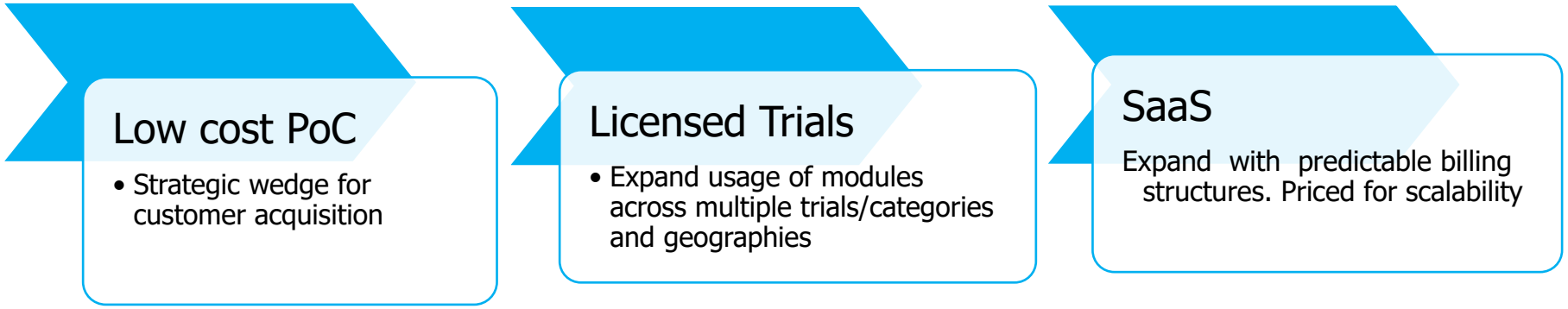
- **Kevin Coker: CEO ProximaCRO**

- *" Blockchain has the opportunity to revolutionize life sciences industry in the same way it has others.*
- *Bloqcube is the only solution I am aware of this approach. They are the future."*

- **Shruti Konda: CEO Koncord Clinical Research Services**

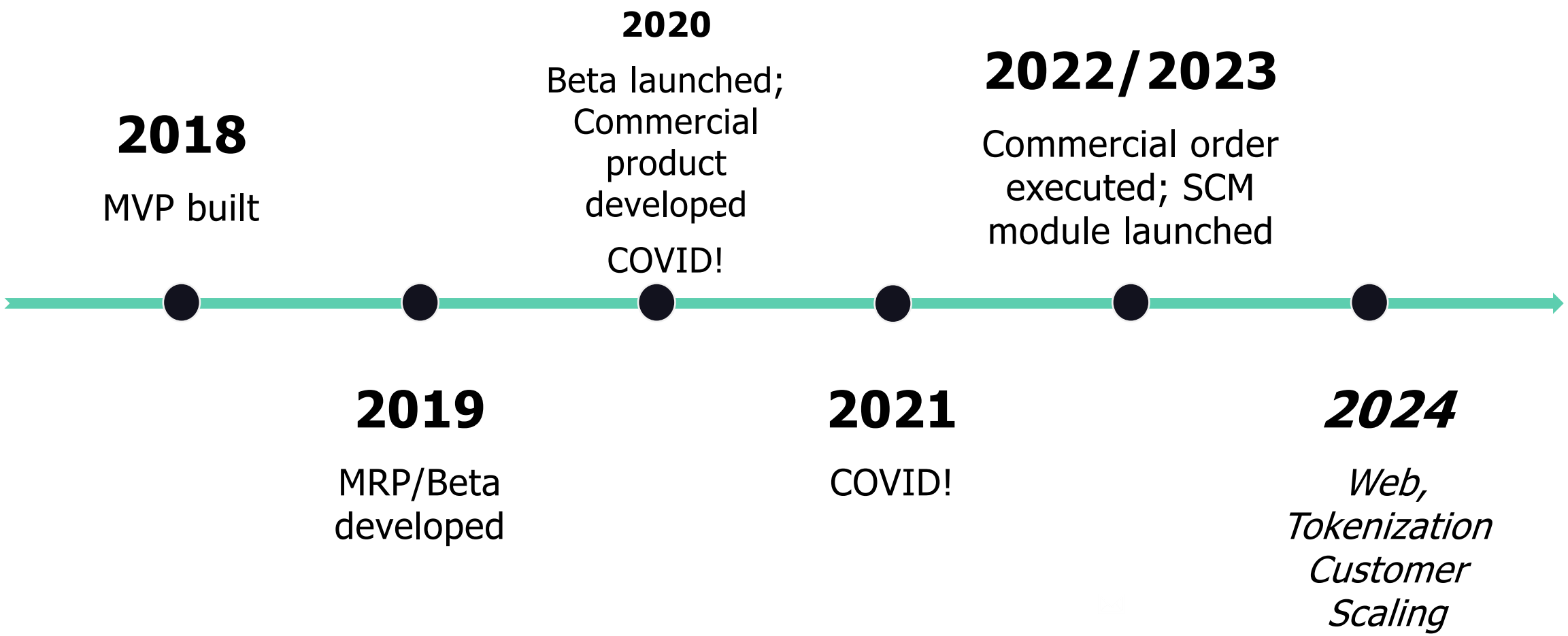
- *" I have had the opportunity to use the Bloqcube system for an end-to-end trial with a boutique CRO. The system helped me track site activities and made monitoring so much easier. It also helped run the trial in multiple countries without any obstacles and helped drive compliance to the protocol. One of the best features of this system is query management tool that helped cut down timelines. I am very happy with Bloqcube's ability to meet the CROs expectation and make my job easier".*

Business Model…Revenue extraction $50k-$250k/trial Modules Licensing to Platform SaaS

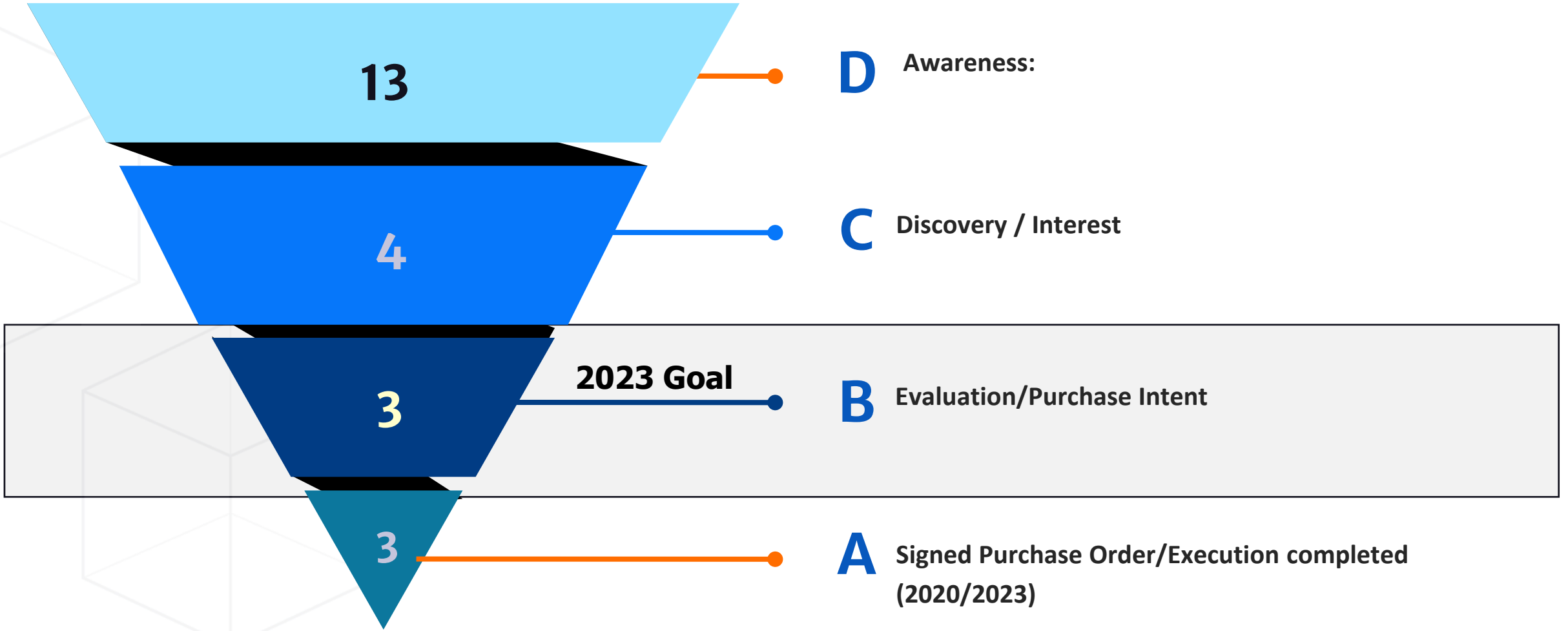


Three Revenue elements: Usage, Maintenance, Value Added Resellers

Product Roadmap



Sales Funnel: 20 Leads; pace accelerating compared to last year



*PoC expected

Execution team in place with deep domain expertise for an unfair advantage

Leadership Team

Rama K. Rao MBA
CEO/Founder; ex CFO Novartis Pharma Canada/Russia
Ex-Head Novartis Oncology Global Development Finance

Dr. Prem K. Narang
PhD, ex-Head of Novartis Oncology, Global Regulatory Affairs

Rajan Nagarajan MBA
Advisor – Digital Transformation, IT and SCM
ex-SVP, CTI Foods (Ex-Kellogg/ Kraft/ Philips/ Ford)

Scientific Advisory Board

Dr. Thomas Bock
Ex-CEO HeritX; ex-GMA Head, Novartis Oncology, Celgene; Co-Founder, APandemic

Dr. Stephen Cunningham
Ex-Head of Novartis USA Clinical Development & Medical Affairs; Co-Founder and CDO Engrail Therapeutics

Dr. Alex Cahana
Blockchain Expert UN/CEFACT, Economic Commission Europe

..+10 additional FTEs in Tech Development/Validation;
CSO and CMO recruiting in progress

Rama K Rao B.Tech. MBA

- Mr. Rama K Rao is the CEO and Founder of Bloqcube, a US-based company which pioneers Web 3.0 blockchain based clinical trial management systems.
- He is a senior executive with 28 years of extensive experience in the pharmaceutical industry with Eli Lilly and Novartis & won multiple awards
- He worked in multiplicity of senior executive roles including:
  - Global Head for Clinical Development Finance for Novartis Oncology,
  - Head of Clinical Development Finance Novartis USA
  - CFO of Novartis Pharma in Canada/Russia
- He also set up and later led, the R&D Finance College at Novartis that trained over 150 associates globally during his tenure. He has lived in eight countries and speaks four languages including French.
- He is a thought leader and has presented/chaired at various conferences in Geneva, Austin, Dubai, Hyderabad, London, Bio IT World, Boston and SCOPE Florida; he was recognized (June 2020) by *PharmaVoice* in their article on "New Era of Clinical Trials". *Silicon India* and *CIO Review* recognized Bloqcube as one of the top 20 most promising companies 2021 and was nominated for the Prix Galien for Digital Health Startup category

Advisors and Board

- 1.Dr. Alex Cahana

https://www.linkedin.com/in/dr-alex-cahana-health-blockchanger/

- 2.Dr. Prem Narang

https://www.linkedin.com/in/prem-narang-ph-d-fcp/

- 3.Rajan Nagarajan

https://www.linkedin.com/in/rajan-nagarajan/

- 4. Dr. Gita Mathur

https://www.sjsu.edu/people/gita.mathur/vitae/

- 5.Dr. Stan Kachnowski PhD MPA

https://www.linkedin.com/in/stan-kachnowski-phd-mpa-903a6b1a7/

- 6.Dr. Stephen Cunningham

https://www.linkedin.com/in/stephen-cunningham-md/

- 7.Dr. Thomas Bock

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

- 8.Thierry Schrang

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

- 9.Peter Droc

https://www.linkedin.com/in/peter-droc-7829b01/

- 10. Dr. Deborah Soule

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

- 11. Naney Pandit

https://www.linkedin.com/in/naney-pandit-b14a583/

- 12. Robin Roberts

https://www.linkedin.com/in/robin-roberts-393a934b/

- 13. Vinay Parchure

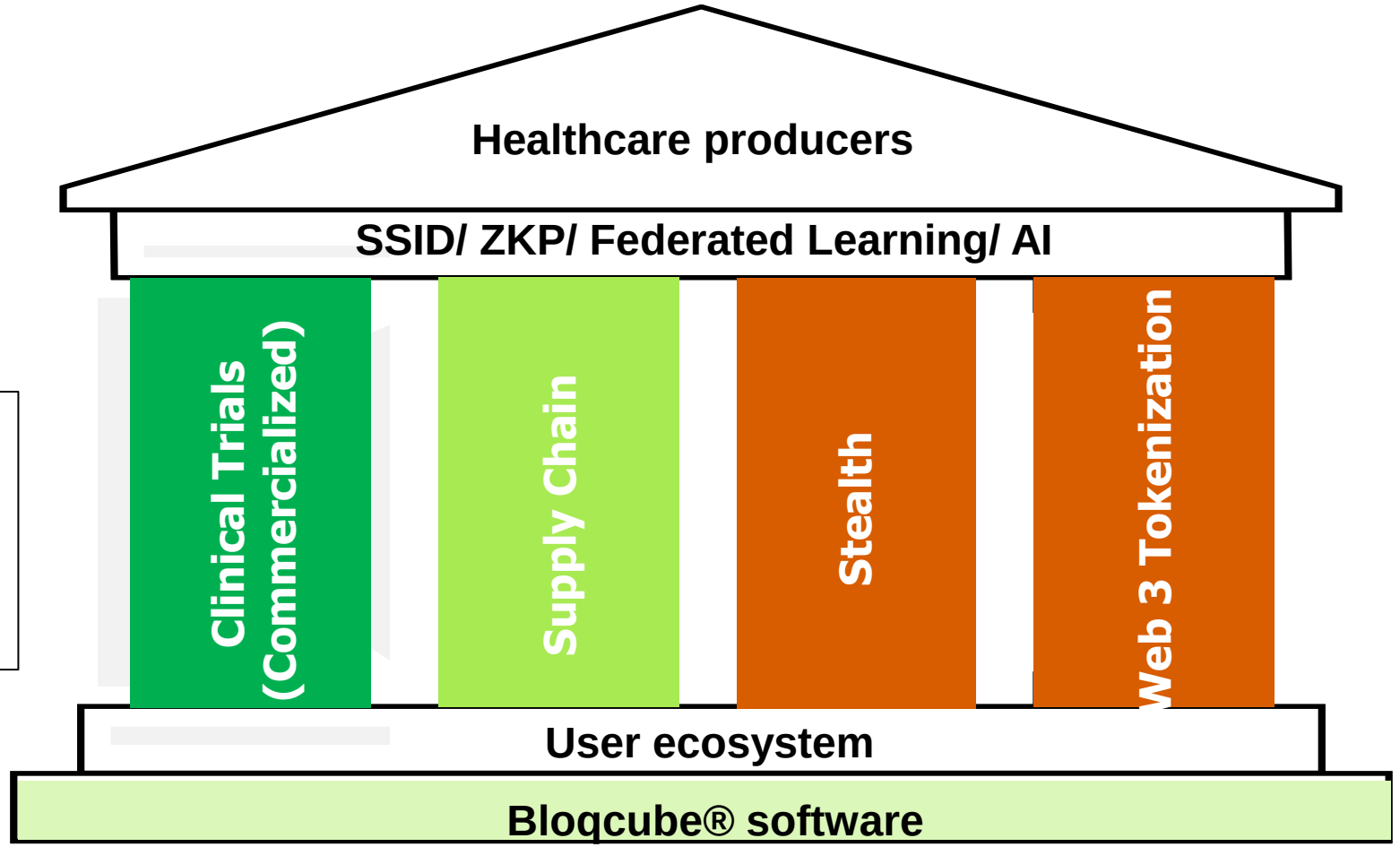
https://www.linkedin.com/in/fdaguru/

- 14. Dr. Scott Motyka

https://www.linkedin.com/in/scott-motyka-253a5023/

- **Clinical Advisory Board**: 1, 2,6,7
- **Diversity/Equity/Inclusion & Digital Transformation Advisory Board**: 5, 10, 11,12
- **Regulatory and CSV Board**: 2, 13
- **IT and Commercial Advisory Board**: 3, 4, 8, 9, 14

Transformational Vision: Healthcare Consumers to Healthcare Producers



Web 3.0

Web 2.0

Initial execution focus: Clinical Trials Operations systems

Commercialized **Technical PoC** **Stealth**

Thank You

Rama K Rao

CEO/Founder

Piscataway, NJ

+1 908 656 5548
rama@blogcube.com

Lancet article- Blockchain and clinical trials

FDA draft guidelines issued on Decentralized Trials

Decentralized Clinical Trials for Drugs, Biological Products, and Devices

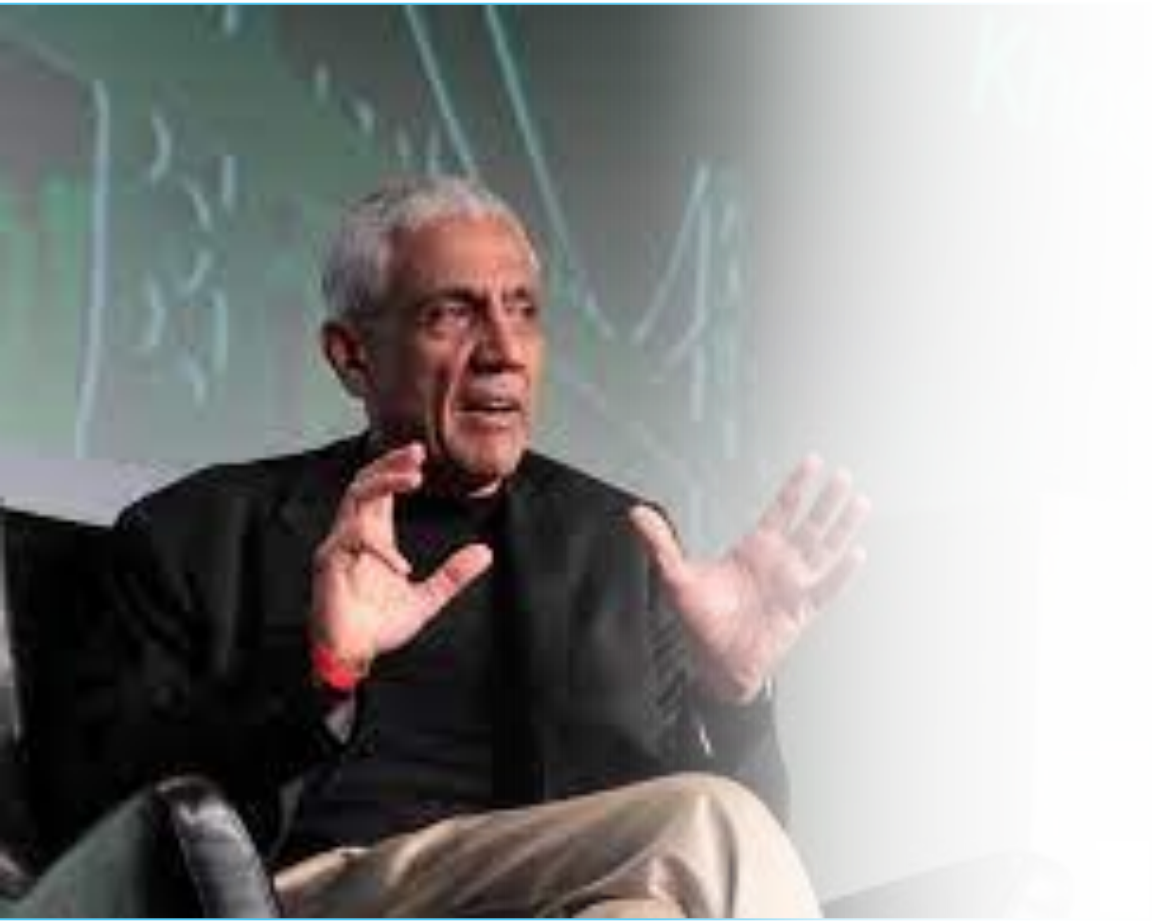
Guidance for Industry, Investigators, and Other Stakeholders

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

Vinod Khosla – Drive data security by blockchain

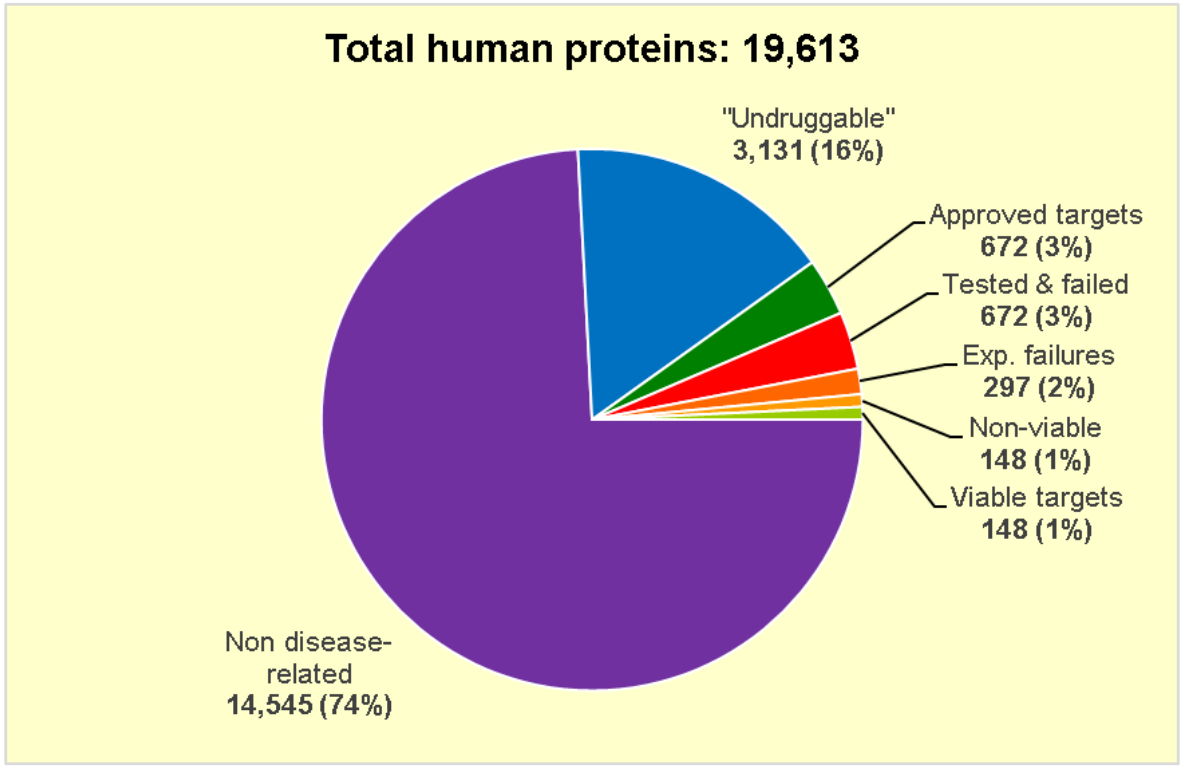


en, through this system, permission them to
vhoever wants their data with the
ssion.

nately the only real solution to data
some form of blockchain. Make it only
e end user. It's also a great point of
ut it some place where the user has control

v places the blockchain is extremely valuable
uted to us as opposed to trusting some
osla

Pharma Discovery – Diminishing Targets

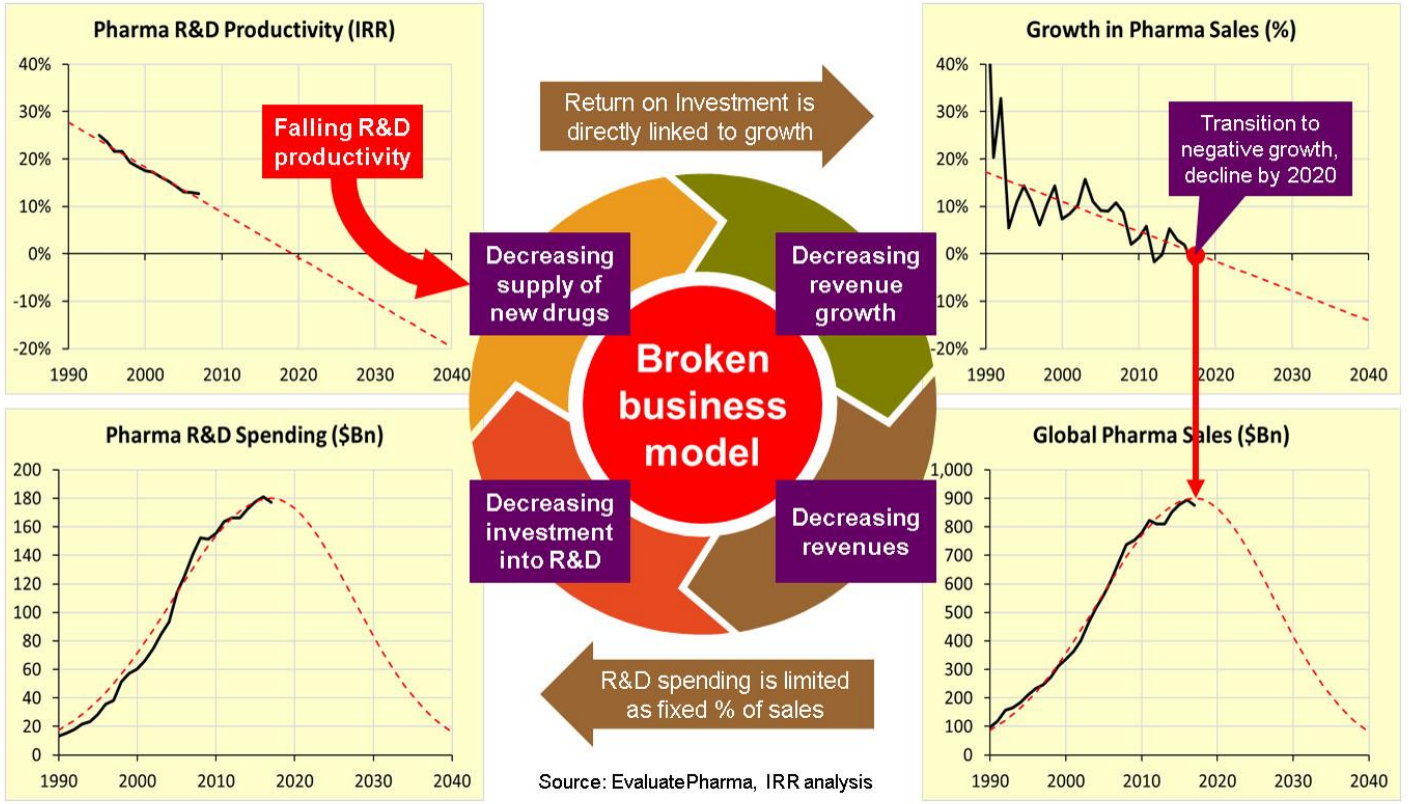


Source: Human Protein Atlas, DrugBank, KS analysis

Source: "Pharma's broken business model – an industry on the brink of terminal decline"; Scraping the barrel in drug discovery ;Kevin Stott, Director R&D Portfolio Management
Nov 17, 2017

Pharma Discovery – Diminishing Returns

A strategic view……



…Challenging times requiring new solutions

Source: "Pharma's broken business model – an industry on the brink of terminal decline"; Scraping the barrel in drug discovery'; Kelvin Stott, Director R&D Portfolio Management; Nov 17, 2017
Dr. Alex Cahana – https://medium.com/crypto-oracle/blockchain-might-be-the-only-thing-that-will-fix-pharma-conversations-with-pharma-execs-and-358cab458be7

Sources:

1. Society for Clinical Research Sites(SCRS)
   (a) 'Why is clinical source data still collected on paper' – May 2017' White Paper; 'CenterWatch, SCRS & Clinical Ink. Research Site Source Survey. December 2016. [n = 656]'
   (b) (b)"90% of sites create study specific source forms…. Of those sites, 96% still use paper-based approaches when creating source forms and collecting source data"; Page 1
   (c) "Site Payment" May 2016. White paper by SCRS Panel co chaired by Messrs. Kelly Cummings, Claire Grace, David Vulcano

- 2. " In a survey conducted by SCRS in 2016 sites are reporting a profit margin of 13%,…. In addition to receiving payments well after they complete their work, holdbacks mean that more than the entire profit margin on a study may not be realized until months after the study ends….unrealistic burden on the site to remain cash positive or even neutral. It is no wonder that guaranteed payment in 30 days is considered "very valuable" by 77% of research sites doing more than 5 studies per year. Yet only 28% of site payments are monthly
- 3.'The Road to Positive R&D returns' David, Tramontin, Zemmel – McKInsy Quarterly Feb 2010
- 4."$8m revenue loss per day" – 'Drug Development Technology' www.drugdevelopment-technology.com/features/ 'Clinical trial delays: America's patient recruitment dilemma' by Daniel Garrun
- 5. *Parexel Biopharmaceutical R&D statistical source book 2016/2017 Page247-250. 'Clinical Trial Costs: An examination of costs by Phase, Therapeutic area and the key contributing factors' Eastern Research Group July 2014
- 6. *https://www.fda.gov/downloads/training/guidancewebinars/ucm383657.pdf
- 7. : Parexel Biopharmaceutical R&D Statistical Sourcebook 2016/17; Pg. 66-67."A global CRO market model to 2018: A 2015 analysis"- UBS Invest Research, Jan 2015

Why now….. Unhappy Firms investigating shift

In a CTMS* survey by Veeva they found:

- 99% of respondents had issues with existing CTMS* systems
  - Of which almost 50% had issues with Site /Study management reporting
  - 25% had issues with financial management
- Their top drivers to improve CTMS were:
  - Better visibility, Proactive risk identification, better study analytics, costs savings, eTMF* integration, Ease of use, Improved governance/oversight, EDC* integration

Source: https://www.veeva.com/resources/industry-survey-shows-87-of-clinical-operations-leaders-taking-action-to-unify-clinical-processes/

Current technologies have not provided sustainable solutions

TMF-Trial Master Forms' EDC- Electronic Data Capture

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