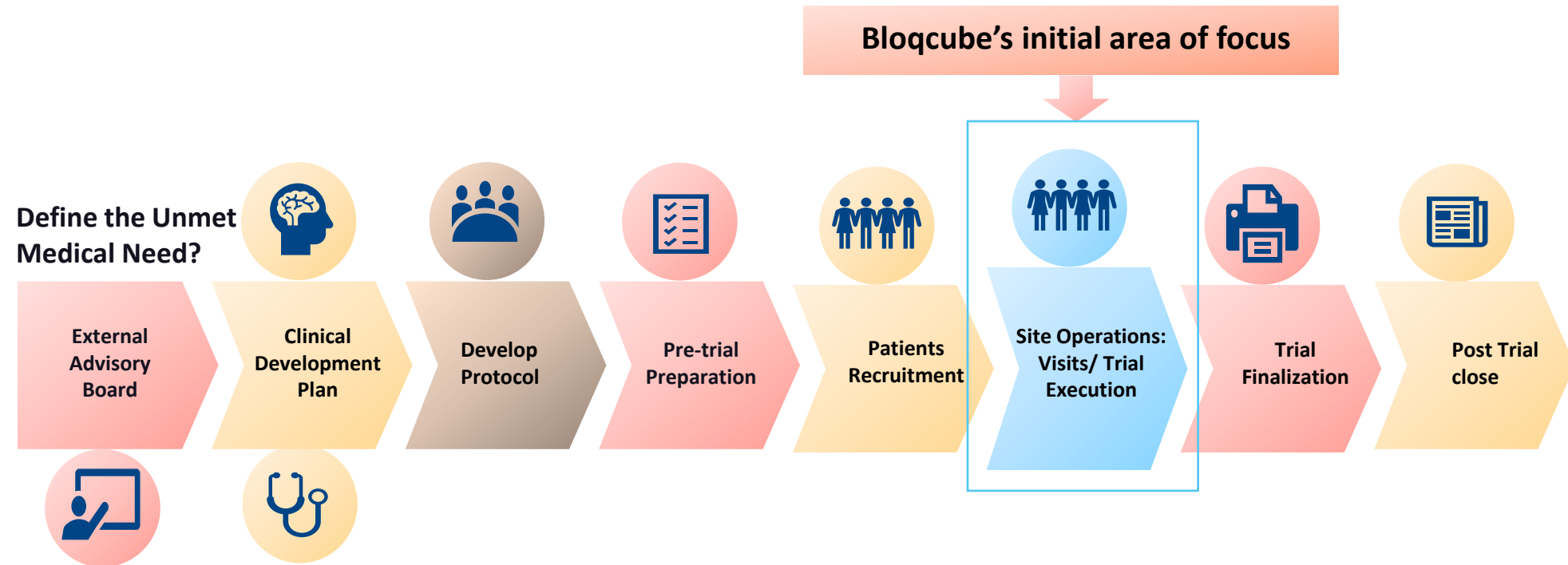




Bloqcube®: B2B Clinical Trials Software Platform for Accelerating Clinical Trials Product Features Journey: 2018-2022



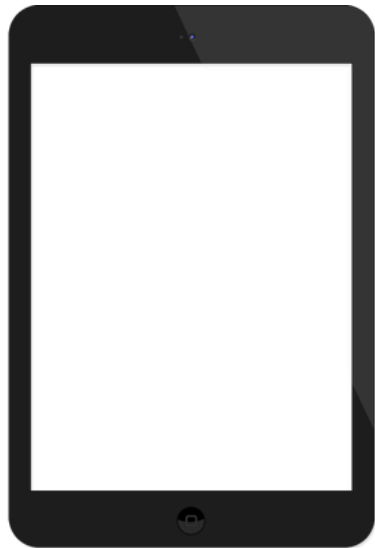
Clinical trials by Pharma companies are costly, inefficient, time consuming with multiple systems used



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

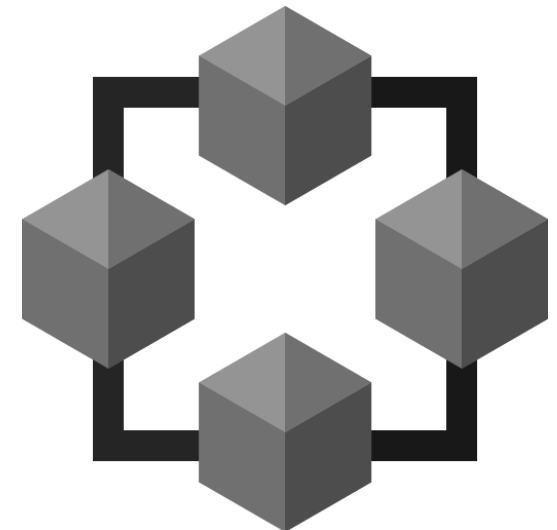


21CFR Part 11 compliant

Cloud / Decentralized



Blockchain enabled



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

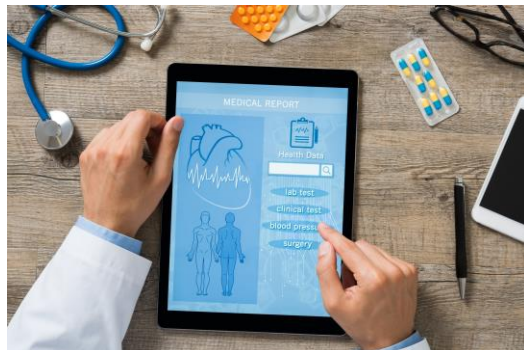
Lifescience

product owner:

Concerned that
cumbersome
inefficient processes
delaying
productivity



Site admin: Multi
system paper
processes for
Regulatory binders



Physician / Study coordinator:

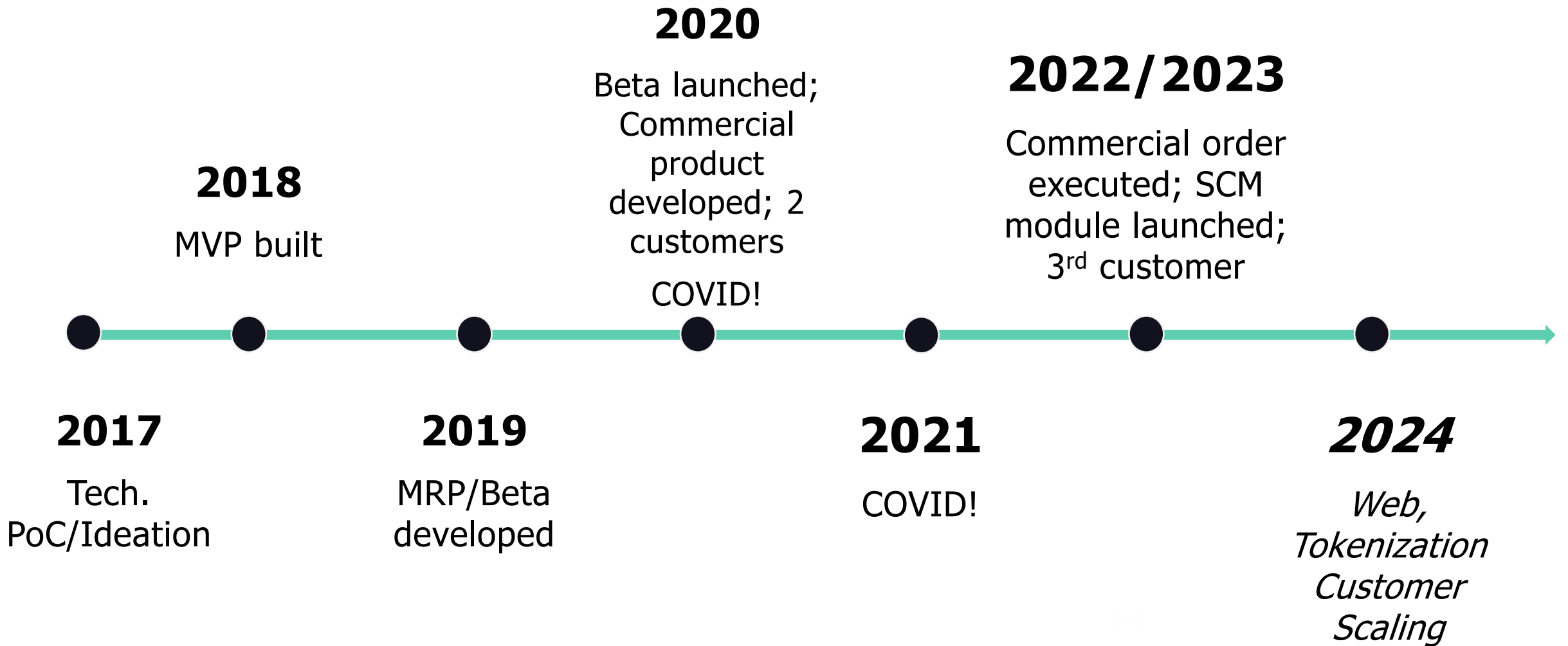
Concerned about
regulatory compliance
and study delivery and
getting paid late



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



Product Roadmap



BLOCKCHAINS ENCRYPTING DATA

QuickTime Player

File Edit View Window Help

9:41 AM

100%

BQ1202 Trial

M_24 Case Report Form

Save

Protocol BQ1202

Doctor John Physician

Age 24 years

Gender Male

Height 5.6

Race Caucasian

Baseline Details

Tumor Stage II

BRAF Mutation Yes

Prior Chemo BRAF Inhibitor

Longest diameter of lesion 3.0 cm

Cycle 1

Start Date 04.08.2017

I.V. Dose of BQ administered in mg

DLT

Longest diameter of lesion (0 - 4.0) cm

AE Grade 3

Enter outcome & intervention

Enter outcome & intervention

AE Grade 4

Enter outcome & intervention

ibm-bcs-passenger-prod.mybluemix.net

Network · 45f31..

Copy

Tips

[Connected to Validating Peer 0]

3.4

BLOCKS SPEED

1.6

TRANSACTION ACTIVITY

0

DEPLOYMENTS

16

INVOCATIONS

Deployments	Invocations	Date	Type	UUID	Chaincode ID	Payload
0	2					registerPatient \$359b883c-6e2c-4706-b639-27b6986fef8
0	2					@972973bd4cb5b0cd6122f8d74be6c96208b721ae191571252f62d067530ebb2c
0	2					NCKco6WaiNKd/o6u7TvtlvkbsGU1x79DSHvILN9iQRSITXDvvg3Ckb0YJqX+HzR0z7ZYmhEuq76LUn4xy5PaFGJzelF+LDPaanbBO8PluFzy5c8CwjPU5QuftJkGK55qLHgPx+NpSx4xcFdHGYYEZ/7CcYHJ5jQJwjUopb+3k8+wrznNVqIV/1dgg3y1P7953M1ViM6g6zuo9bVNS+OmFyLJRpiKiumQ+IghaB4SBvr3OS5ncJOdUheYW+X+8/AVs1exws1LNziOgOeY4e6AbMth2+Sv+txl81GZeopPkIhVhli/LutO9Gr457GX5bCvXqJEW
0	1	08/03 09:21am UTC	INVOKE	2a60f3eeab534b98e931c05ebfd	ae3956cd8a2...	
0	2					
0	2					

1days 30min ago

147

0

1

1days 30min ago

146

0

1

1days 34min ago

145

0

2

1days ago

144

0

2

BLOCK CHAIN DRIVEN BLOCKS

How does it work? Technical Proof of Concept 2017; first use of Hyperledger V0.6

Trial setup

BQ1202 Trial [View List of Patients](#)

Created Date :	Jul 27, 6:15 PM
No. of Patients :	6
Total Fixed Cost	\$40.0
Fixed Cost Consumed	\$40
Total Variable Cost	\$360.0
Variable Cost Consumed	\$97.5
Total Budget	\$400
Budget Consumed	\$137

Lifescience product owner

Regulatory binders/site checks

BQ1202 Trial

Enrolled Patients

M_39	Created on Aug 1, 2:35 PM
Last updated on Aug 1, 2:35 PM	
M_43	Created on Aug 1, 2:35 PM
Last updated on Aug 1, 2:35 PM	
M_56	Created on Jul 31, 1:18 PM
Last updated on Jul 31, 1:18 PM	
M_90	Created on Jul 27, 9:15 PM
Last updated on Jul 27, 9:15 PM	
M_34	Created on Jul 27, 8:54 PM
Last updated on Jul 27, 8:54 PM	

Site admin

Direct Data Capture

M_25 Case Report Form [Save](#)

Protocol	Bq2345	Doctor	John Physician
Age	25 years	Gender	Male
Height	5.6	Race	Caucasian

Baseline Details

Tumor Stage	II
BRAF Mutation	Yes
Prior Chemo	Interferon
Longest diameter of lesion	8.0 cm

Cycle 1 Longest diameter of lesion **8.000 cm** Start Date **Jul 28, 9:24 AM** [v](#)

Cycle 2

Start Date **03.08.2017**

I.V. Dose of BQ administered in mg

DLT

Longest diameter of lesion (0-10) cm

AE Grade 3

<input type="text"/>	Enter outcome & intervention
<input type="text"/>	Enter outcome & intervention

AE Grade 4

<input type="text"/>	Enter outcome & intervention
----------------------	------------------------------

**Physician Investigator
Study coordinator**

Real time safety signals

Adverse Event Reports

AE Term	Grade 3	Grade 4
Anemia	2	0
Nausea	4	2
Vomiting	0	2
Decreased WBC	0	1
Increased ALT	0	0
Increased AST	0	0

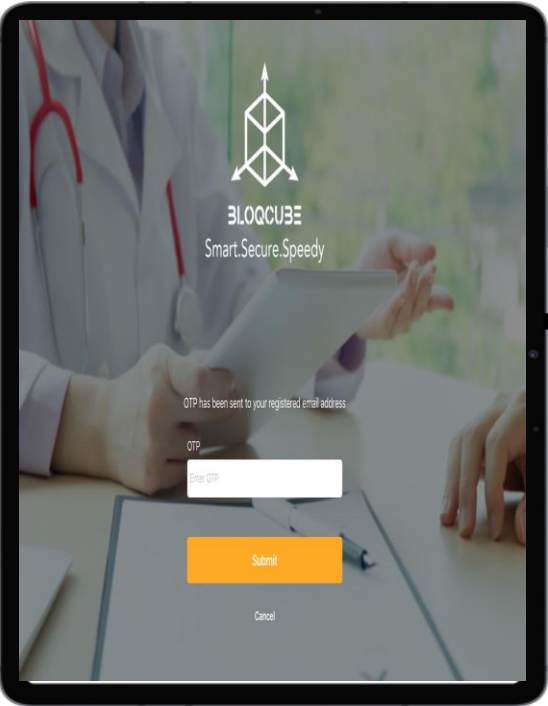
Severe Adverse Event Reports

SAE Term	Count
Cardiopulmonary failure	3
Pneumonia	5
Cerebrovascular accident	0
Cardiac arrest	0
Leukopenia, Neutropenia, Thrombocytopenia shock	0

**Monitors/QA/Safety
Boards:**

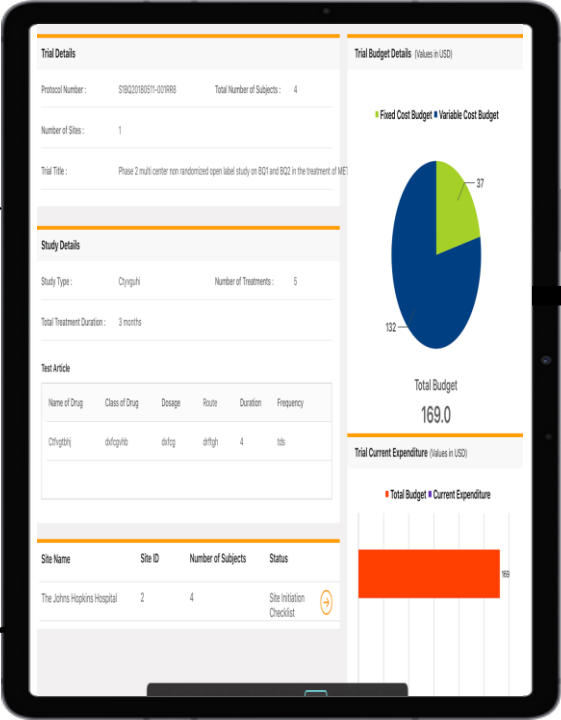
How does it work? MVP 2018

Trial setup



Lifescience product owner

Regulatory binders/site checks



Site admin

Direct Data Capture

Trial Title	Protocol Number	Number of Sites	Number of Subjects	Total Budget	Current Expenditure
Start Date - End Date					
BQ2017 A phase 2 multi center non random...	BQ211009	1	10	\$25,765	\$0
05/03/2016 - Ongoing					
A Phase 2 multi center non randomized op...	S18Q2017-001/RR	1	10	\$49,100	\$0
05/07/2016 - Ongoing					
A Phase 2 multi center non randomized op...	S18Q2018-001RRx3	1	10	\$50,400	\$0
05/08/2016 - Ongoing					
phase 2 multi center non randomized open...	S18Q20180511-001...	1	10	\$32,300	\$0
05/11/2016 - Ongoing					
Phase 2 multi center non randomized open...	S18Q20180511-001...	1	4	\$419	\$87
05/14/2016 - Ongoing					

Physician Investigator
Study coordinator

Real time SDV Monitoring

Monitors/QA/Safety
Boards:

Beta developed 2019 /2020: First DCT clinical study on blockchain in the world

Trial setup: eConsent



Lifescience product owner

Regulatory binders/site checks

Subject Details

Back View Consent Export CSV Visit 2

Basic Details

Protocol ID 15-256-IEC-26-PP-2019

Site ID 1

Serial number 58

Subject ID BQS115-256-IEC-26-PP-2019058

Created At 11/20/2019 18:00:11

Name of subject [REDACTED]

Reference Number 058/kkm

Age 46

Gender Female

Location Type Rural

Address Vetrivel nagar villianur main road embalam

Contact Number [REDACTED]

Social Demographic Details

Religion Hindu

Site admin

Direct Data Capture

Foot 0.0

SDSCA :: Foot Care

Will you really in the last seven days and you check your feet?

0

On how many of the last seven days did you check the inside of your shoes?

0

Smoking 0

SDSCA :: Smoking

Have you smoked a cigarette/ bidi - even one puff, during the past 7 days

No

PHQ 2 2

Patient Health Questionnaire 2 (PHQ 2)

Little interest or pleasure in doing things

Several days

Feeling down, depressed or hopeless

Several days

PSQ 0

Problem Solving Questionnaire

Over the past 1 week, how often did you carry a medical identification card?

Not at all

**Physician Investigator
Study coordinator**

Real time monitoring

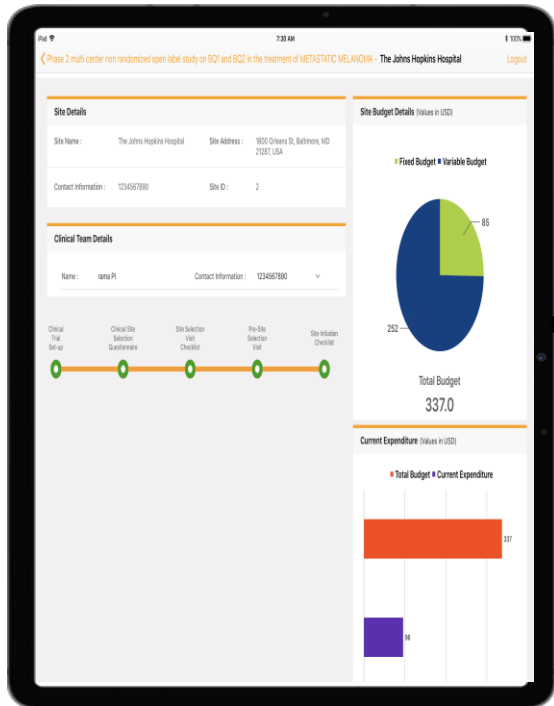
Patient Details Export Enroll

Subjects	Consent	Demog.	CRF	Approved	Visit 2	Transc.
kalavathy BQS115-256-IEC-26-PP-2019159	✓	✓	✓	✓	⚠	⚠
kalavathy BQS115-256-IEC-26-PP-2019158	⚠	⚠	⚠	⚠	⚠	⚠
lakshmi BQS115-256-IEC-26-PP-2019157	✓	✓	✓	✓	⚠	⚠
Rajavalli BQS115-256-IEC-26-PP-2019156	✓	✓	✓	✓	⚠	⚠
muthulakshmi BQS115-256-IEC-26-PP-2019155	✓	✓	✓	✓	⚠	⚠
ramu BQS115-256-IEC-26-PP-2019154	✓	✓	✓	✓	⚠	⚠
saravanan BQS115-256-IEC-26-PP-2019153	✓	✓	✓	✓	⚠	⚠
lakshmi BQS115-256-IEC-26-PP-2019152	✓	✓	✓	✓	⚠	⚠

**Monitors/QA/Safety
Boards:**

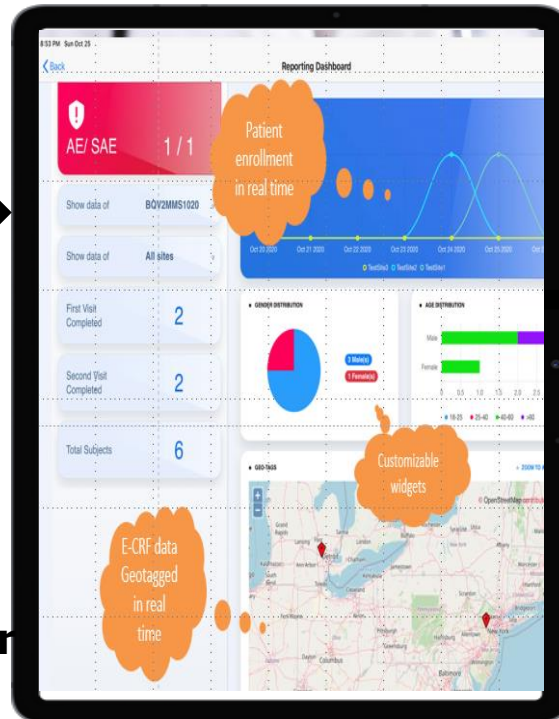
How does it work? Commercial FDA Part 11 Compliant Product 2020/2021

Trial setup



Lifescience product owner

High level Transparency



Site admin

Direct Data Capture



Physician Investigator
Study coordinator

Real time safety signals



Monitors/QA/Safety
Boards:

How does it work? Users' journey 2022/2023

Trial setup

The screenshot shows the 'Clinical Trial Set-up' app interface. It has three tabs: '1. Basic Details', '2. Add Site Details', and '3. Summary'. The '2. Add Site Details' tab is active. It contains two main sections: 'Site Details' and 'Clinical Team Details'. The 'Site Details' section includes fields for Site Name, Select Site (dropdown), Number of Subjects, Enter number of Subjects, Site Number, Fax, Site Admin Name, Select Site Admin(s) (dropdown), and Site Address. The 'Clinical Team Details' section includes fields for Trial Team Member (dropdown), Contact information, Role (dropdown), Document, Title, and Version. There is an '+ Add Participant' button at the bottom right.

Lifescience product owner

Regulatory binders/site checks

The screenshot shows the 'Clinical Trial Set-up' app interface, specifically the '2. Add Site Details' tab. It features a section titled 'Documents by Site' with a '+ Add New' button. Below this, there are rows for 'Signed clinical trial agreement', 'IRB regulatory filings, communications and approval letters', 'Signed form 1572', 'SOPs', and 'CDAs', each with a document icon. At the bottom, there are 'Reset', 'Add New Site', and 'Continue' buttons.

Site admin

Direct Data Capture

The screenshot shows the 'Case Report Form' app interface. It has tabs for 'Subject Details', 'Case Report Form', and 'Data Audit'. The 'Case Report Form' tab is active. It shows a 'WORC Survey' with a 'Date of Assessment' of 30/09/2022. There are radio buttons for 'Was WORC Survey performed?' (Yes/No). Below is a 'Section A: Physical Symptoms' with three questions: '1. How much sharp pain do you experience in your shoulder?' (scale 1-5), '2. How much constant, nagging pain do you experience in your shoulder?' (scale 1-2), and '3. How much weakness do you experience in your shoulder?' (scale 1-8). Each question has a visual slider with 'no pain' and 'extreme pain' labels.

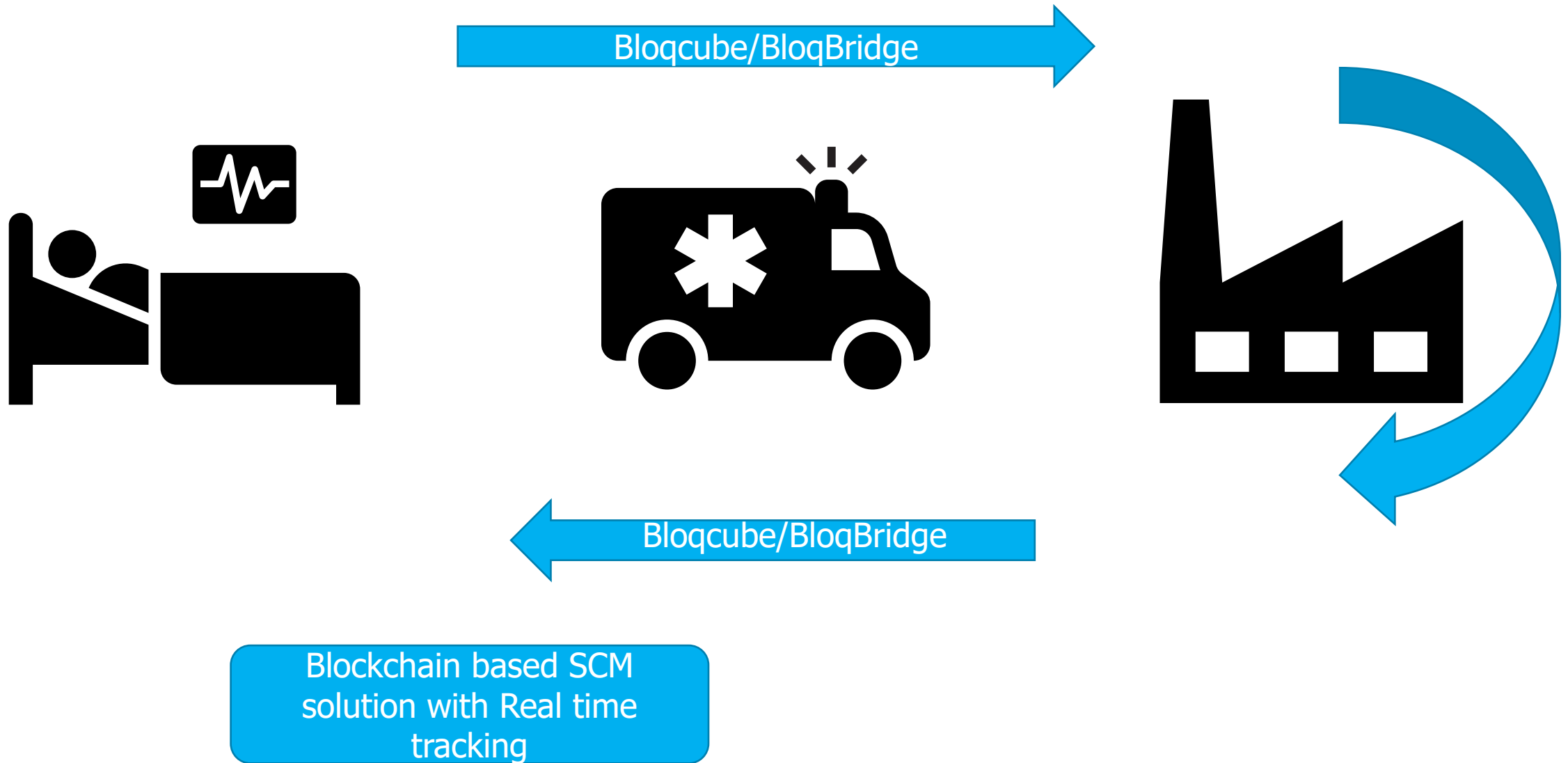
Physician Investigator
Study coordinator

Real time safety signals

The screenshot shows the 'Case Report Form' app interface, specifically the 'Data Audit' tab. It features a section titled 'Serious Adverse Events' with a 'Date of Procedure' of 30/09/2022. It includes several yes/no questions: 'Did the subject experience any serious adverse events?', 'Did the subject experience any serious adverse device effects?', 'Is this an Anticipated Serious Adverse Device Effect?', and 'Is this an Unanticipated Serious Adverse Device Effect?'. Below these are fields for 'SAE Term', 'Onset Date', 'Stop Date', 'Severity', 'Frequency', 'Continuing?', 'Action taken with Study', 'Relationship to Study Device', and 'SAE Narrative'.

Monitors/QA/Safety
Boards:

BloqBridge: Dec 2022 launched



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

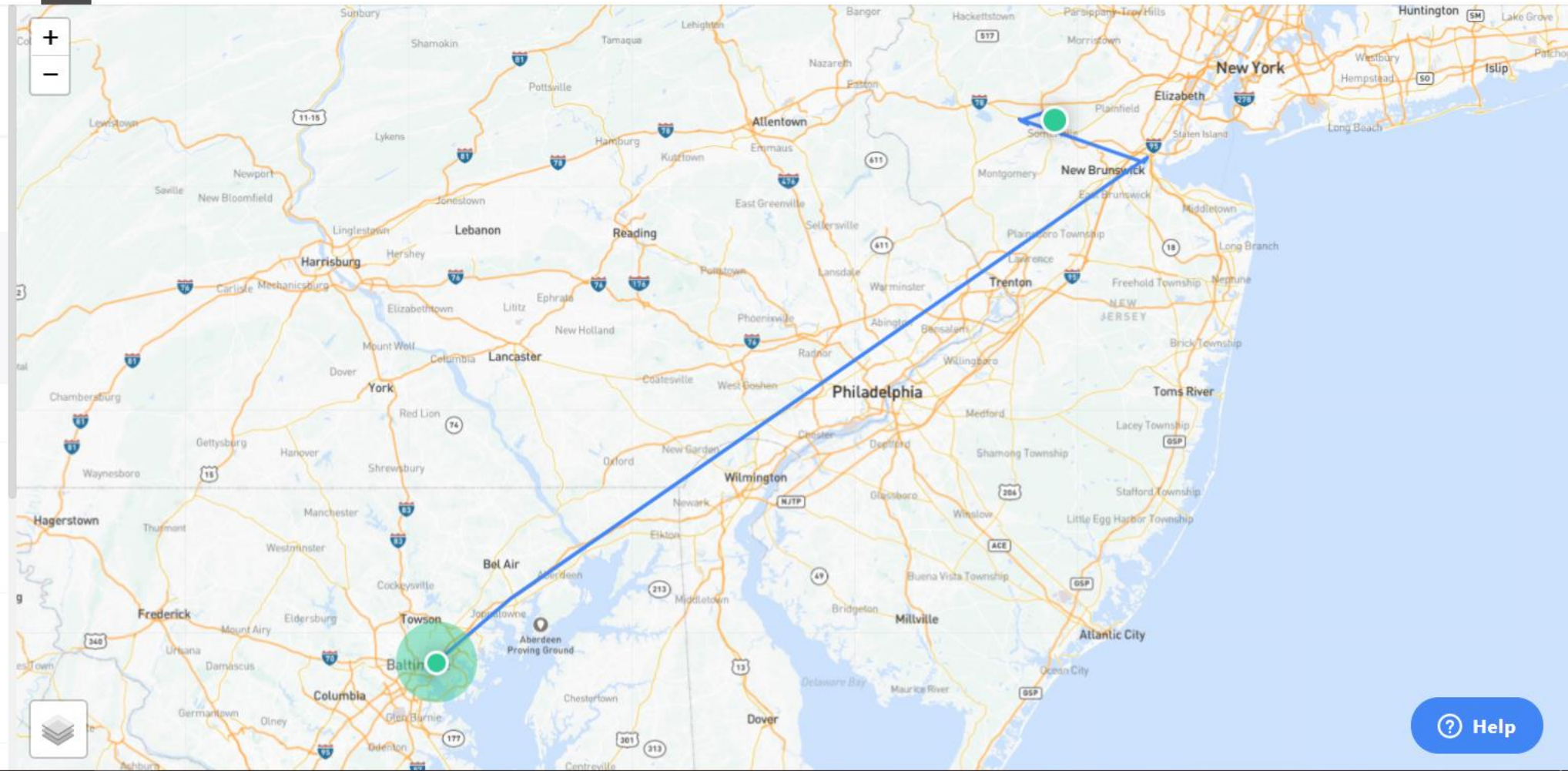
Sensors

Temperature (°C)

7.52

Humidity (%)

44.60



Help

Henry Ford

“ If I had asked people what they wanted they would have said faster horses”



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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, Zimmel – 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 Research, Jan 2015