

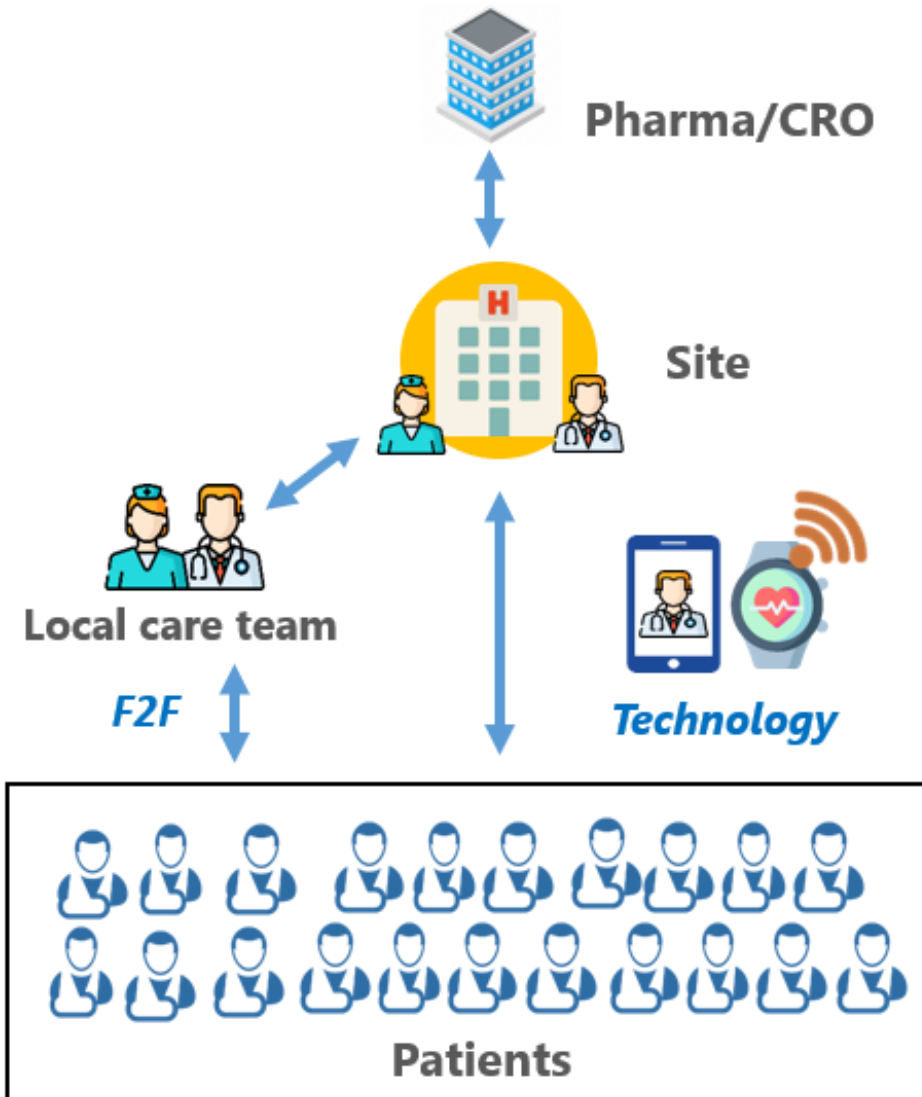
Launching a Healthcare Driven Decentralized Trial *Real-life Use Case*

Hilde Vanaken, PhD
Head Industry Leaders, TCS Life Sciences & Healthcare

PHUSE Single Day Event India, 20th March 2020



Moving from Site-Centric to Patient Centric Approach



Patient Access



Patient Comfort



Data Access



Data Integrity



Time to Market



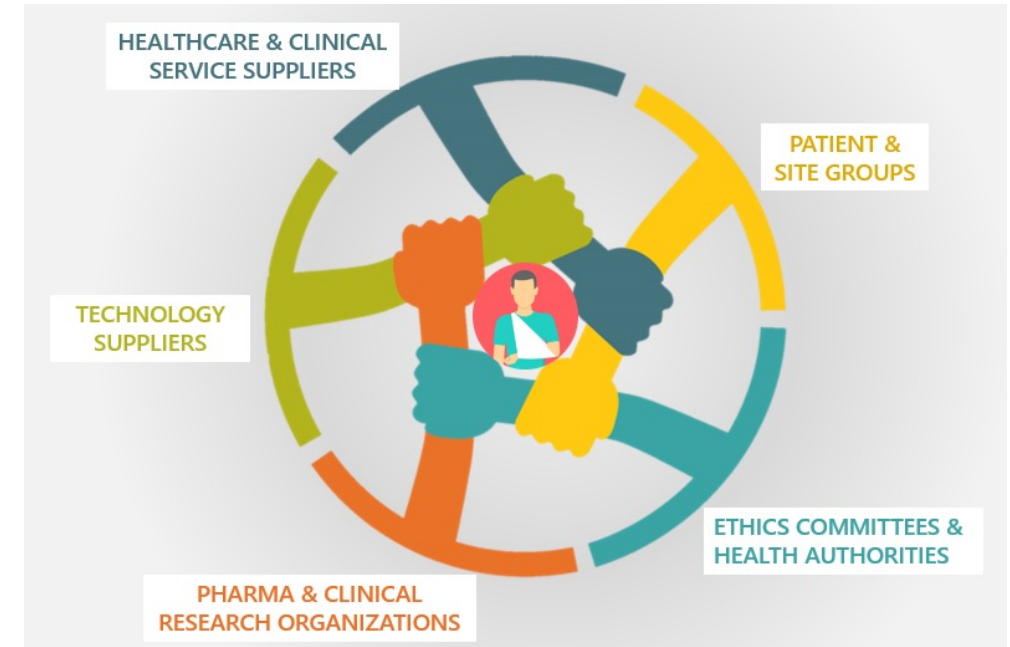
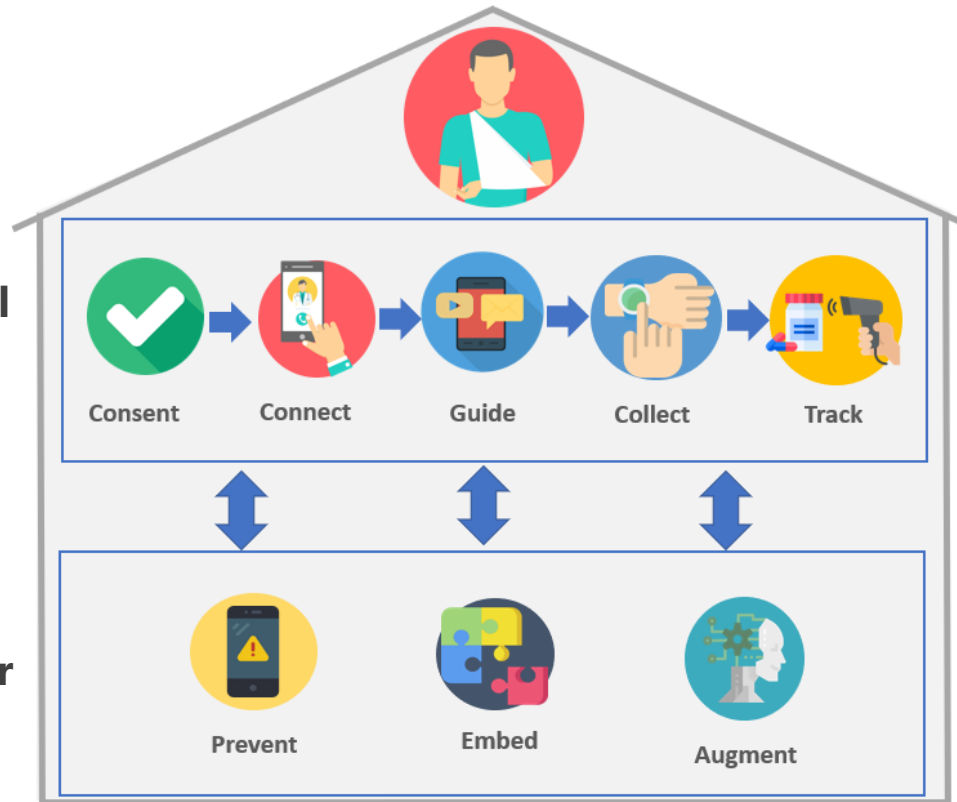
Two Key Success Drivers for Decentralized Trials

Technology

Partnerships

Incorporate clinical trials in patients' personal life

Move clinical research to another dimension



Covid-19 pandemic brought to prominence several factors

TCS' vision on DCT published in PharmaVOICE, *July 2020* & a webinar on 'Shaping the future of Decentralized Trials', *September 2020*

TCS Capabilities & Expertise In Decentralized Trials

Patient & Site Engagement

- eConsent
- Personalized notifications
- Educational material & Audio
- Smart questionnaires
- Smart Site Assistance
- Voice enabled data collection
- Behavioral Insights
- Community Forum

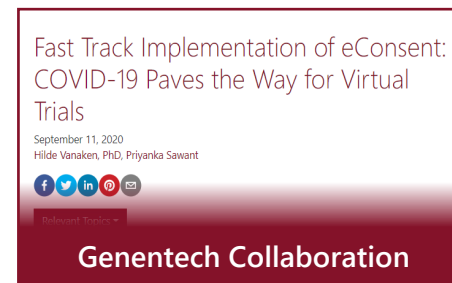
Supply Management

- Digital Label
- Kit Tracking
- Pill/Unit Tracking

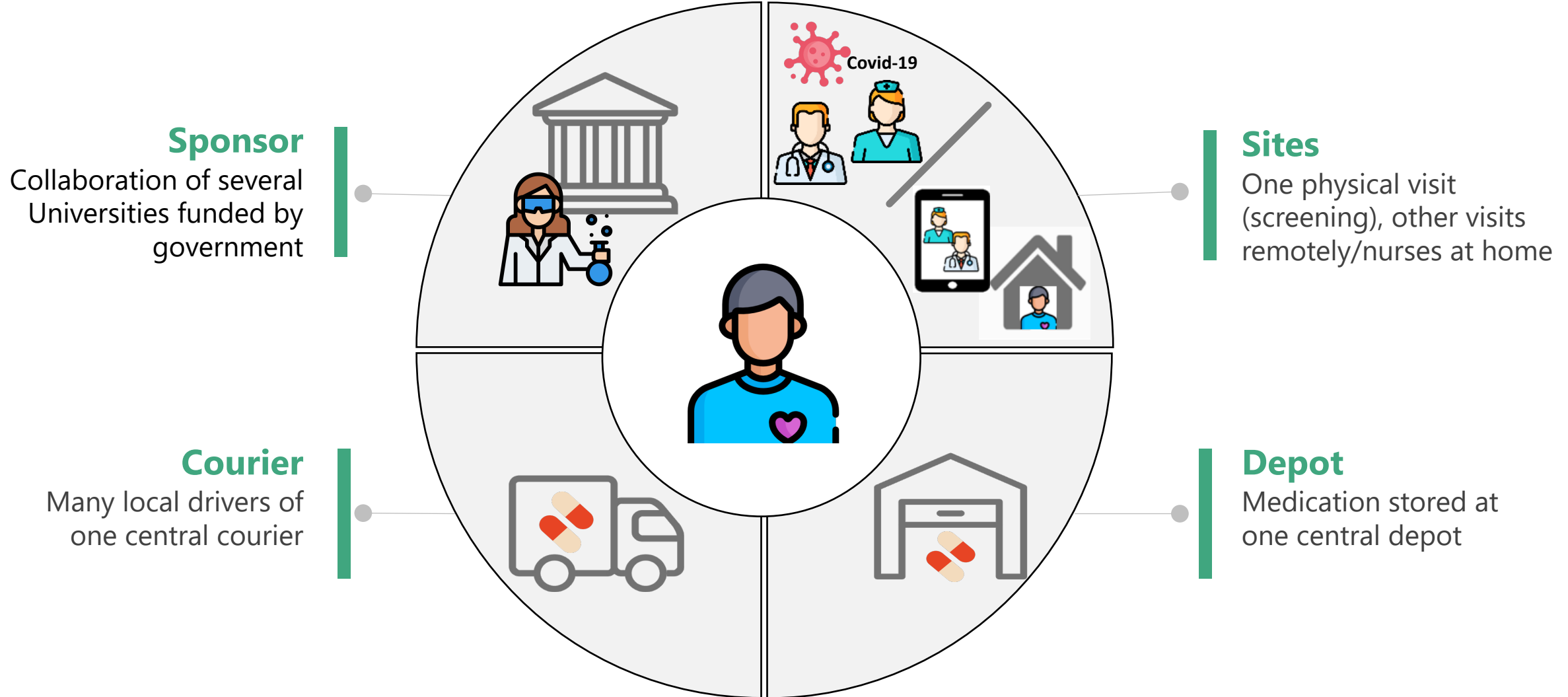
Devices & Connections

- Smart Devices & Wearables
- Digital Biomarkers
- Bio-sample tracking
- Telemedicine & new operational model

- ✓ 8 Top-20 pharma companies
- ✓ 80+ studies (phase I-IV, ≠ TAs)
- ✓ 25+ countries
- ✓ 15 + languages

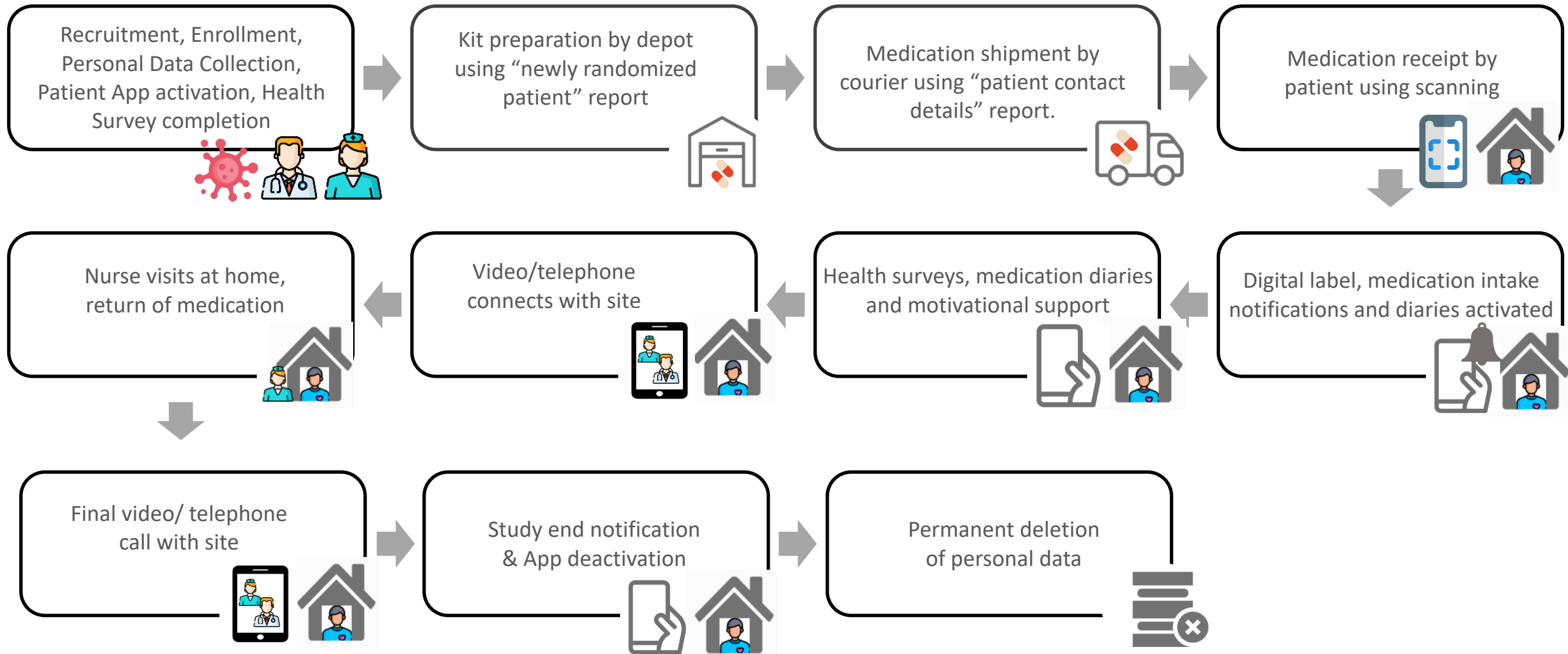


Use Case of Healthcare Driven Decentralized Trial – Key Stakeholders



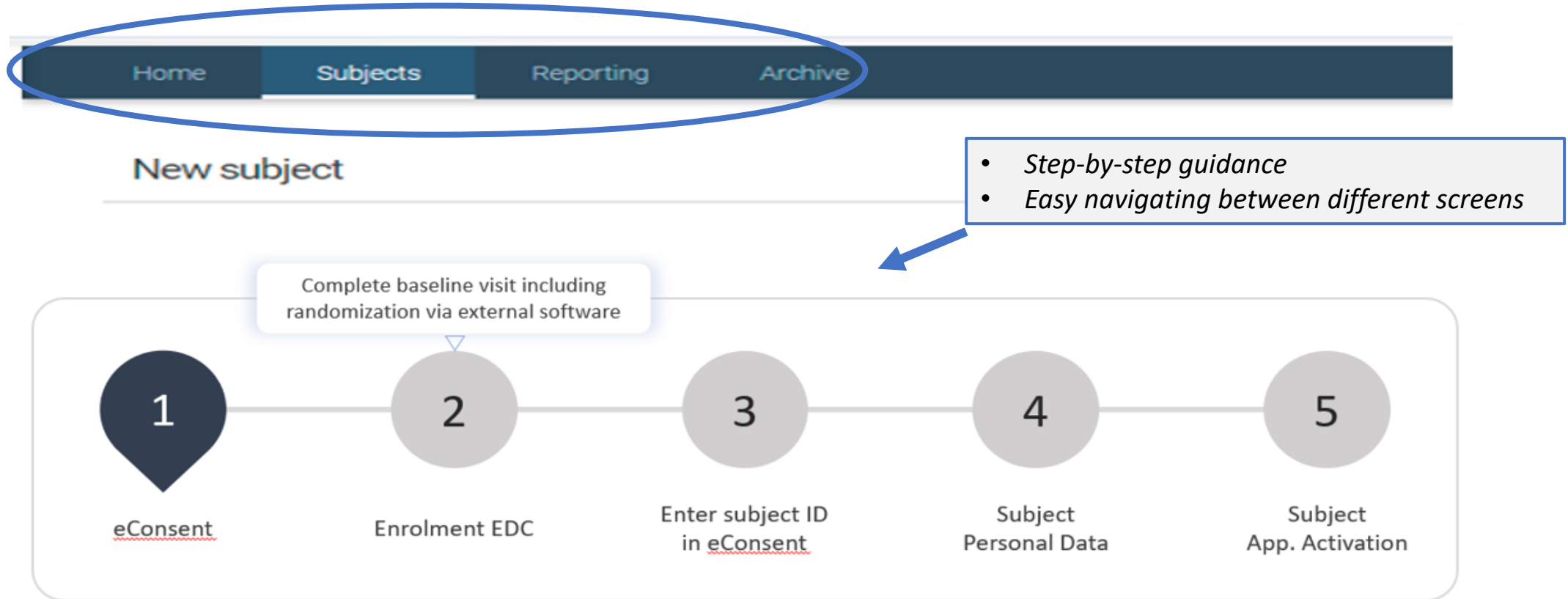
Any Patient, Any Place, Any Time

High Level Process Flow



Using TCS' ADD Data Management & Decentralized Trials solution, First Patient In March 2021

Site Portal: Easy-to-Navigate & Hands-on Guidance



eConsent: Flexibility as a Key Component

Role-based consent creation

Select the persons involved in the consent process

☐ Patient

☐ Legal Authorised Representative

☐ Impartial Witness

☐ Translator

eConsent and Paper consent

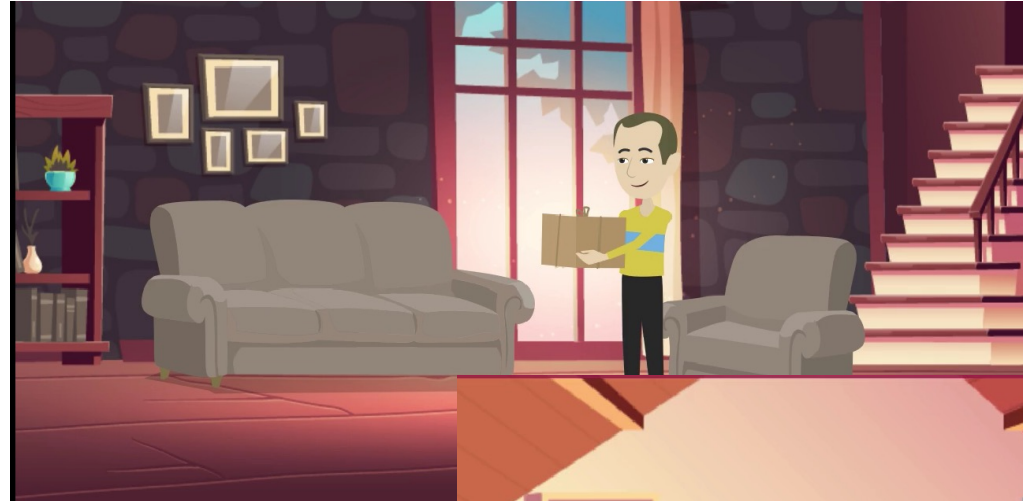


Electronic Consent Process



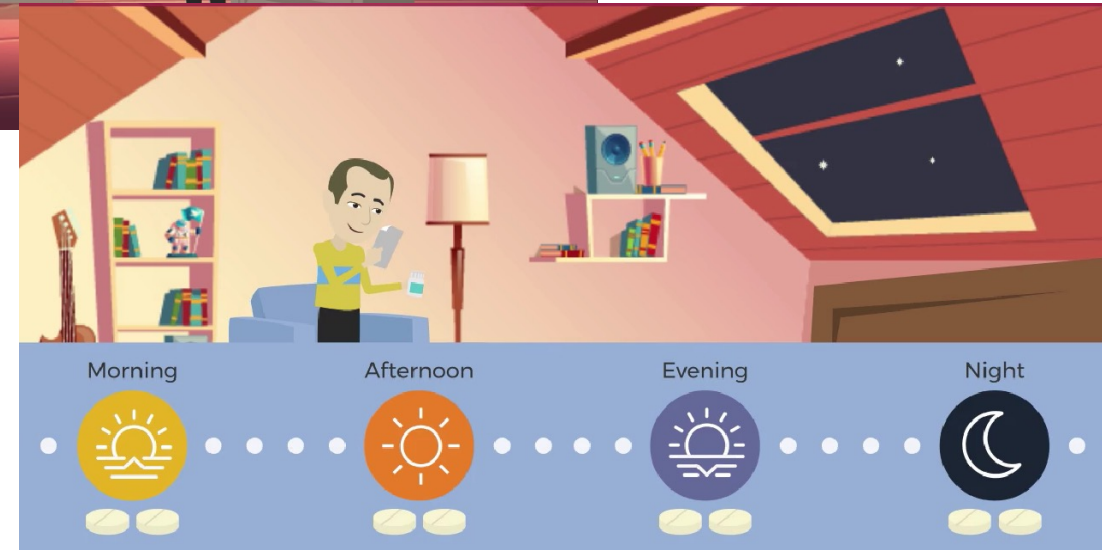
Paper Consent Process

Multimedia



Courier delivers medication @home

Medication intake scheme



Personal Data Collection and Courier Report

HomeSubjectsReportingArchive

← | Subject personal data

Site IDUZ Leuven▼

First NameShawn

Address StreetStreet 179

Address Postal Code4557

Phone Number04793853

Email address if applicable

Subject IDSUBJ_Z_1001

Last NameSmith

Address Number3785

Address Town/CityBrussels

HomeSubjectsReportingArchive

← | Medication kits - Subject shipment address detail report

Configure reportSaved filters

Study ID *--Please select--▼

Show recordsfromuntil11-Mar-2021X

SAVE FILTERRUN REPORT

- First name & Last Name will be auto-populated from eConsent.
- Address, phone number, email address will be permanently deleted after the study

- Courier can select period & run report
- Report can be downloaded in excel and PDF format

Patient's App Activation & App Features

App activation codes

For user ID: 1603378409047 (Patient or legal authorised representative)

Scan the QR code OR Enter the unique code



Unique code

741369

Subject ID

TCS2202

The codes are valid for **2879:59 mins**.

[Regenerate codes](#)

CANCEL BACK DONE

*Generated by Site
QR code or Unique Code*

Study ID - [Yellow Box]

Subject ID - Sub0022



 Medication

 Label

 Health Log

 Learn

 Contact

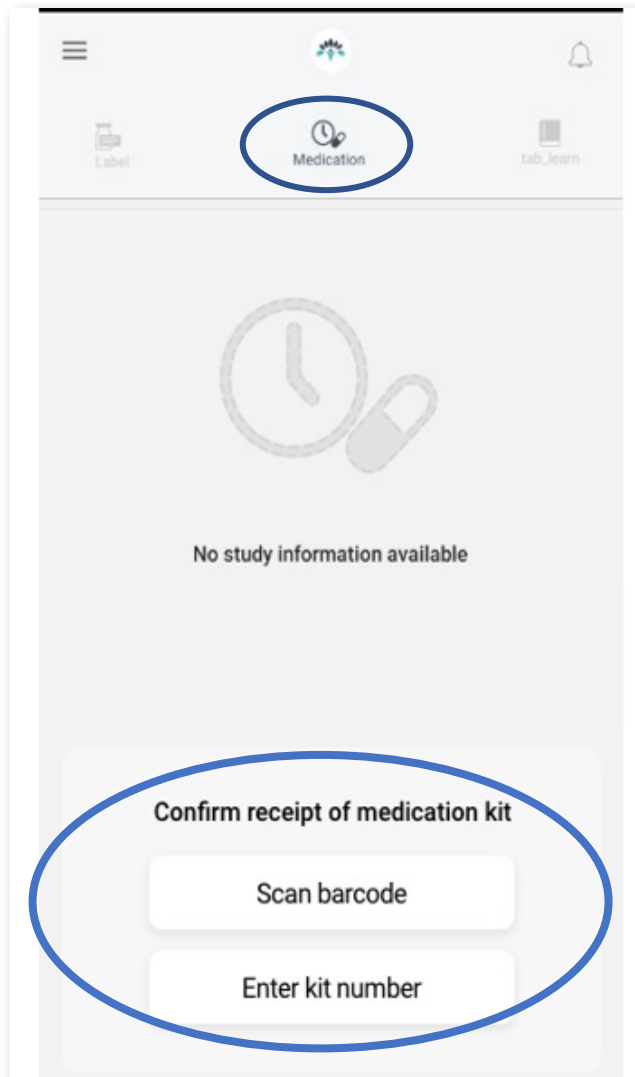
 Privacy policy

 Settings

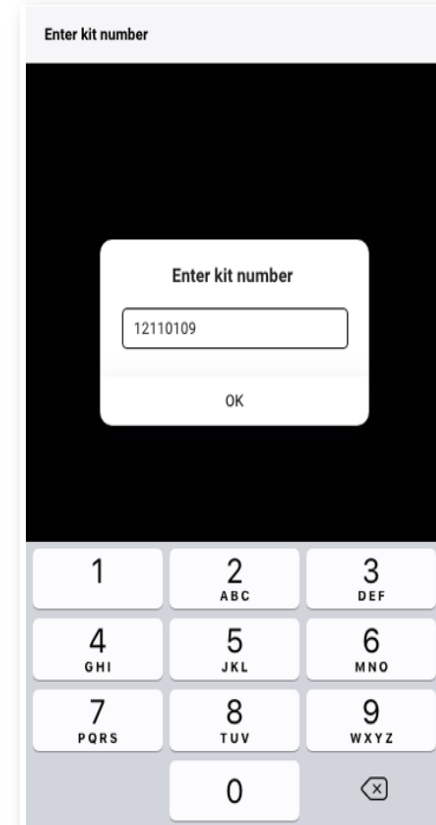
 Log out

- Patient App menu, flexible features, flexible reordering
- Alerts for notifications

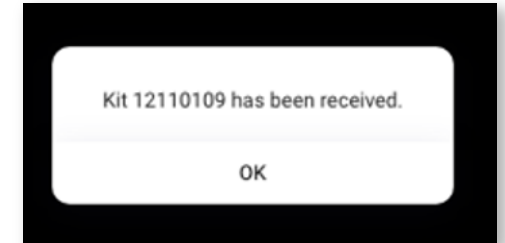
Medication Receipt & Verification by Patient @home



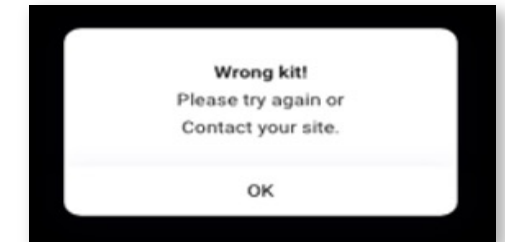
If Scan barcode is selected



If Enter kit number is selected

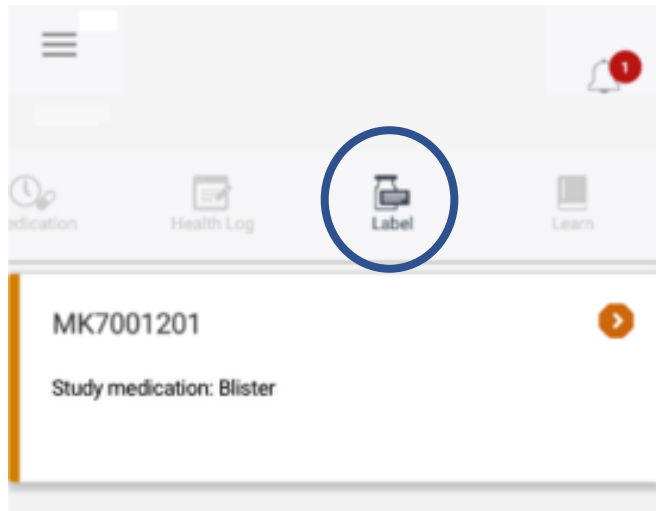


Kit receipt confirmed



Wrong kit message

All-in-One Digital Label in Local Language Pushed To Patient's Phone



New (or updated) Label notification



MK7001201

Study drug
[Yellow box] or placebo

Directions
Oral use, 4 x 2 tablets/day

Dosing instructions
Take 2 tablets 60 minutes before each meal and then before bed, so approximately 4 hrs apart, and at the same time each day

Warning
Keep out of sight of children. For clinical trial use only

Storage conditions
Store at room temperature (15-25 degree C)

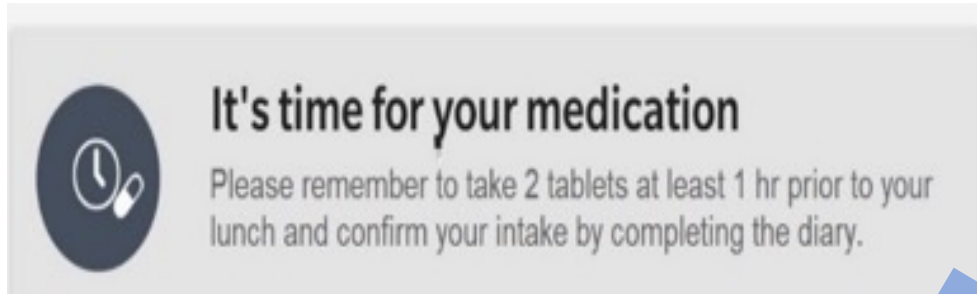
Quantity
60 tablets

Medication No.

↓ I HAVE READ AND UNDERSTOOD THIS

- *Integrated & all-in-one Label (e.g. subject ID from EDC/RTSM)*
- *Easy-to-read with headers and zoom in/out functionality*
- *Flexible reordering, most important info at the top*
- *Confirm ready & understanding*

Personalized Support Throughout The Trial



Personalized treatment notification



Diary entry

Evening

Medication

2 Tablet

Did you take your medication?

YES NO

How many Tablet did you take?

- **2** +

When did you take your medication?

13 Jan 2021 17:00

Medication Diary

Did you take the medication 1 hour before your meal (applicable for morning, noon and evening) *

☒ Yes
☐ No
☐ Not Applicable

SUBMIT

[CANCEL](#)

- If smart packages are used, # tablets, date & time are uploaded automatically.
- Integrated with external smart blisters, smart bottles and smart inhalers in place

Medication Intake Not as Planned with Smart Site Alerts

Diary entry

Evening

Medication

2 Tablet

Did you take your medication?

Why could you not take your medication as planned?

Select a reason ▼

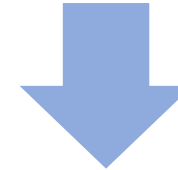
Select a reason

Forgot

Medical

Other

- If No is selected or Not the expected dose was taken, a reason need to be provided.
- In case Medical or Other is selected a free text field will pop up.



Site Alert on Home screen of Site Portal

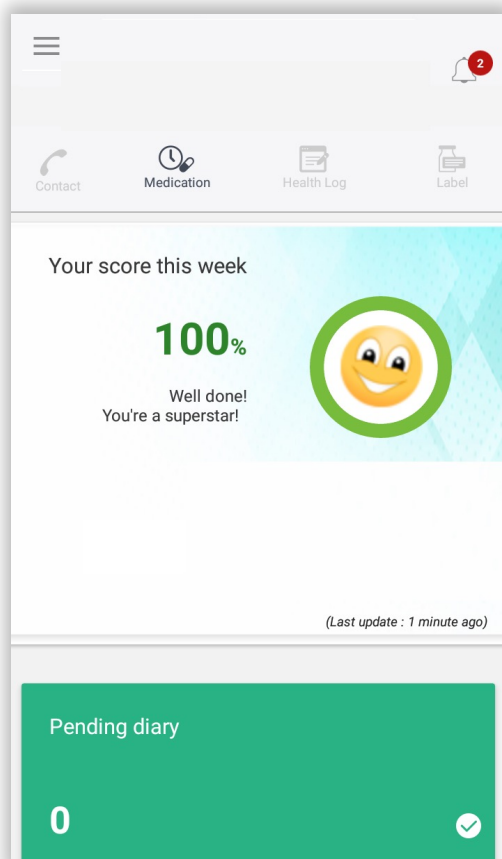
To do

Medical reason selected

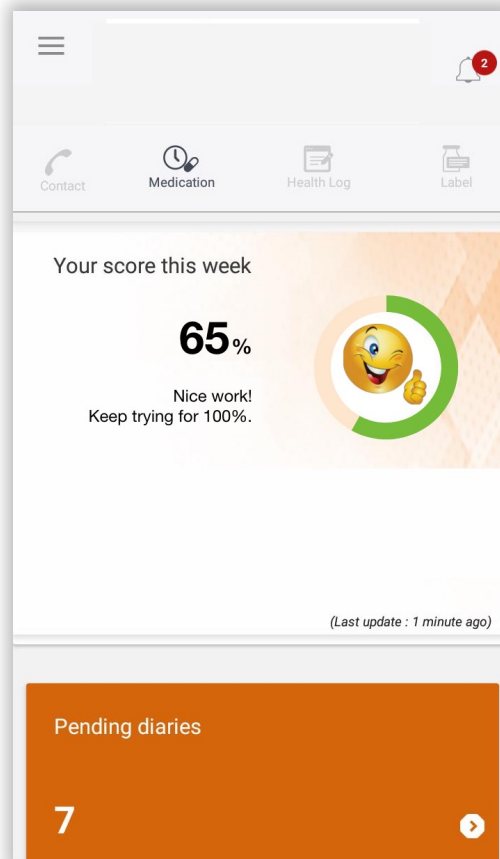
Subject SUB002 from study CCTDEM001 and site A20-1001 has selected "Medical Reason" on the dosing information form for planned dosing instance date 25-Feb-2021 and time 00:15.

25-Feb-2021

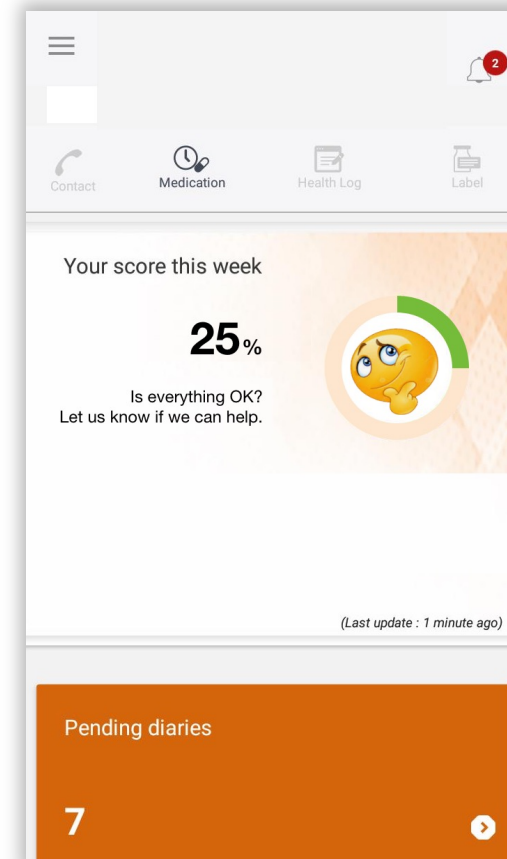
Automated Motivational Messages & Score Card



*(treatment intake compliance
between 75-100%)*



*(treatment intake compliance
between 50-75%)*



*(treatment intake compliance
between 0-50%)*

Real-time Insight & Oversight for Site

The screenshot shows the top navigation bar with four buttons: LAUNCH EDC, SUBJECT INFORMATION, SUBJECT ACTIVITIES (highlighted in dark blue), and MEDICATION ACTIVITIES. Below the navigation bar, there are three dashboard widgets. The first widget, 'Approve adherence data', shows a clock icon, a counter of 0, and the text 'Doses pending site approvals', with a 'VIEW DATA' button. The second widget, 'Labels', shows a pill bottle icon, a counter of 1, and the text 'Pending acknowledgement', with 'PREVIOUS' and 'CURRENT' buttons. The third widget, 'Health logs', shows a document icon, a counter of 0, and the text 'Pending review', with a 'VIEW LOGS' button.

Real-time insight and review of medication intake data, Health surveys, Label confirmations

Real-time insight in kit dispensing, lost/damaged kits, return of kits and flexibility to delay or skip dosing scheme (e.g. based on adverse events)

The screenshot shows the bottom navigation bar with four buttons: LAUNCH EDC, SUBJECT INFORMATION, SUBJECT ACTIVITIES, and MEDICATION ACTIVITIES (highlighted in dark blue). Below the navigation bar, there are four dashboard widgets. The first widget, 'Dispense kits', shows a person icon with a circular arrow, a counter of 0, and the text 'To dispense', with a 'DISPENSE' button. The second widget, 'Collect used kits', shows a person icon with a circular arrow, a counter of 1, and the text 'To collect', with a 'COLLECT' button. The third widget, 'Mark lost/damaged kits', shows a pill bottle icon with a lightning bolt, a counter of 0, and the text 'Lost and damaged', with a 'MARK' button. The fourth widget, 'Modify treatment', shows a pill bottle icon, the text 'Modify treatment (Change dosing regimen, dose skip and dose delay)', a 'Treatment start date' field with 'Day1' and 'Thu Mar 11, 2021', a 'Dosing regimen' field with 'Medication', and a 'MODIFY' button.

Key Takeaways



...are you ready to
join this journey?

Any Questions?

If you are interested to learn more about TCS ADD offerings, please do not hesitate to contact



Dr. Hilde Vanaken
E: hilde.vanaken@tcs.com

E: add.platforms@tcs.com

W: <https://www.tcs.com/advanced-drug-development>