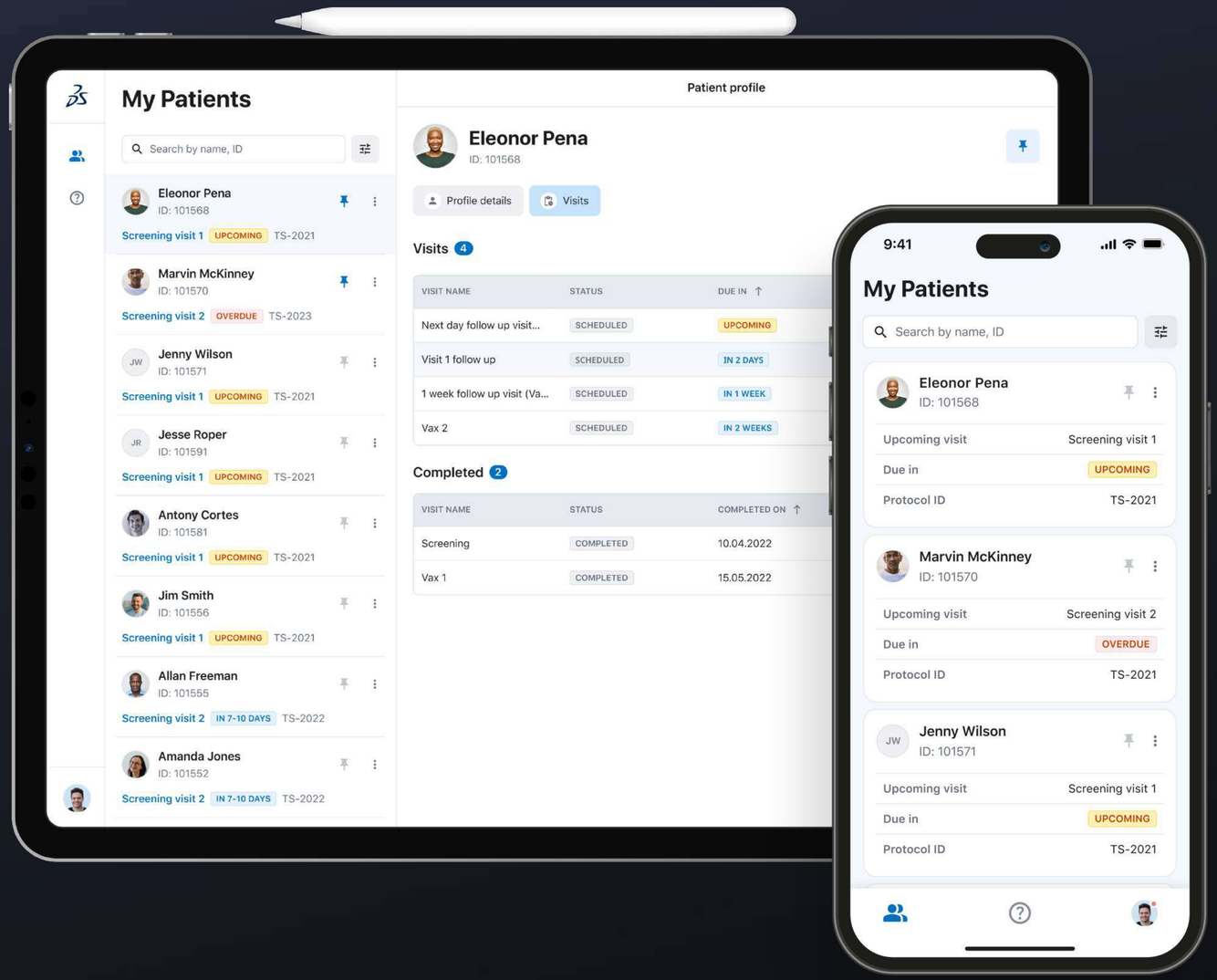
# Medidata app: milestones and high-level roadmap

# What is Medidata app?




**Companion app for site staff to manage patient visits and collect study data (mobile EDC).**

Companion app, Patient management. Vision - replace Rave EDC, eCOA, Patient Cloud.

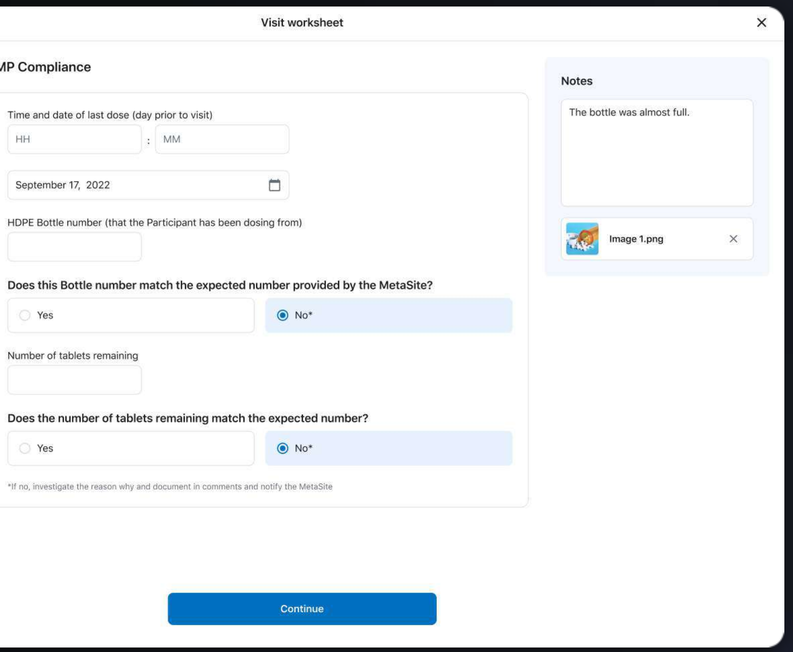
Site staff: CRCs, Nurses, Raters, Home Health Nurses and other personas who interact with patients at a site.

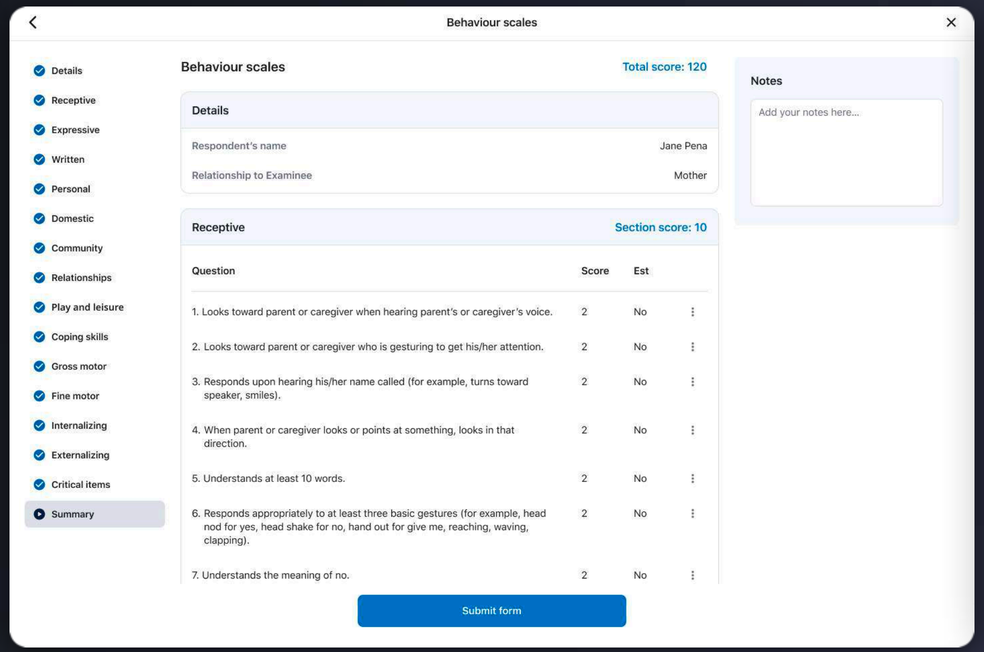
# Medidata platform companion app added value

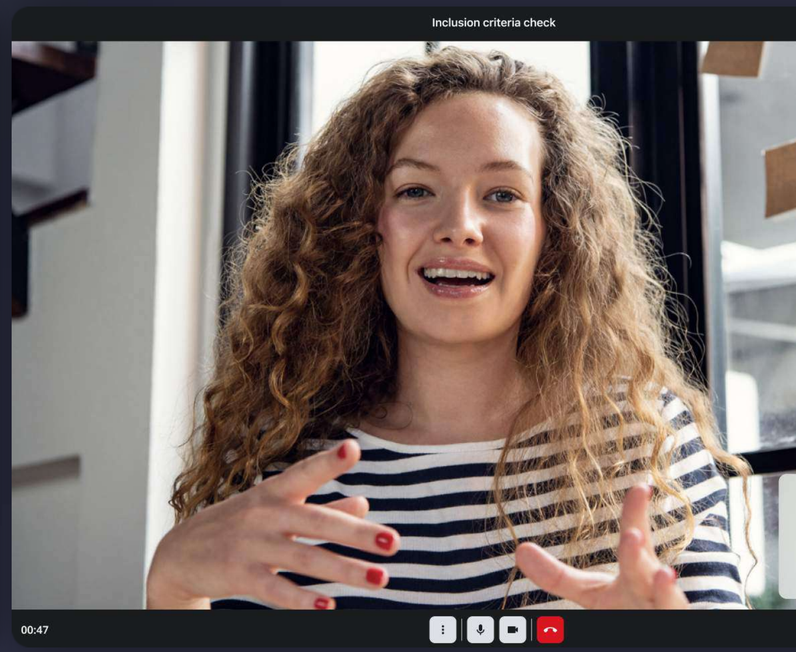
Easy data entry on the go - mobile EDC (incl. multimedia notes)

On-device processing for score calculation and privacy management

Ability to visit patients at their locations (DCT)



# Clinician - Patient experience

status quo & 1X transformation

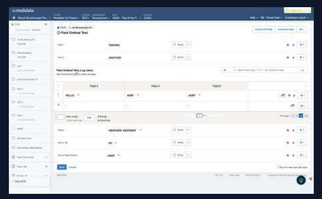
# How it works today

Study Builder, Data Manager

PI / CRC, Nurse, Other Site Staff

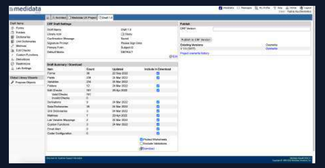
Patient

## Rave Architect



Create and manage ClinRO, PRO, ObsRO and other forms completed at the site.

## Designer



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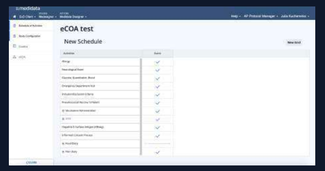
## eCOA Designer

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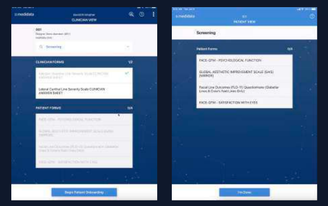
## Patient Cloud



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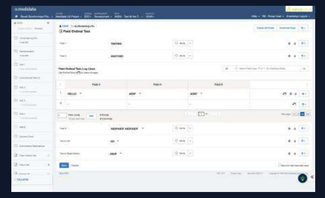

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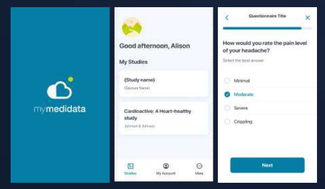
## Other…

Imaging, eConsent, Sensor Cloud etc.

## myMedidata




Smartphone app and web for PRO forms.

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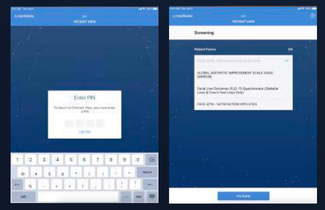


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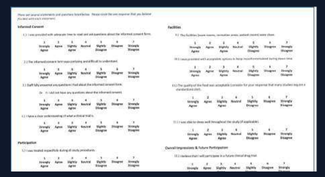

Filling in paper forms at a site.

# 1X transformation path

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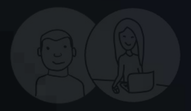

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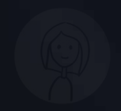
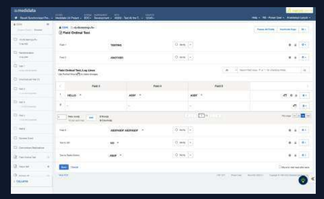


Patient

## Rave Architect



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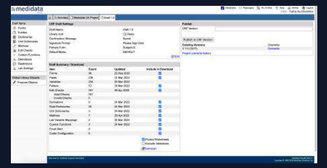

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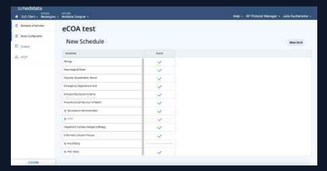

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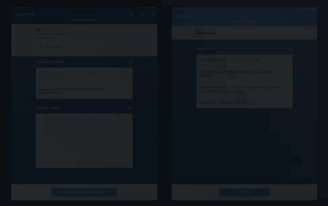

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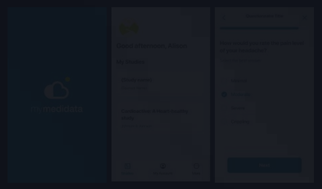

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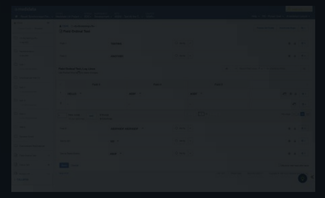

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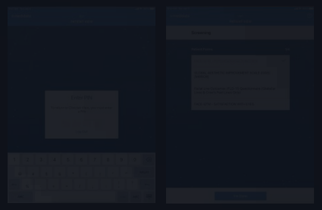

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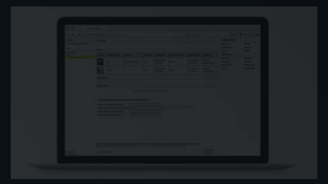

Imaging, eConsent, Sensor Cloud etc.

## Paper forms

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# 1X transformation path

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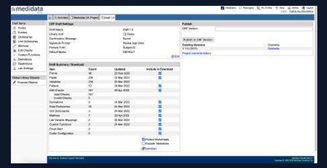

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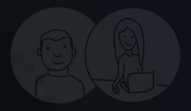

PI / CRC, Nurse, Other Site Staff

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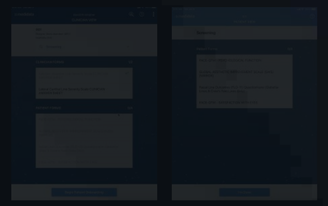

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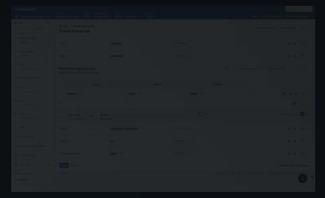

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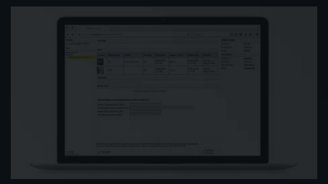

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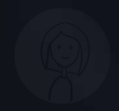

Patient

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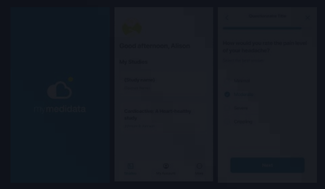

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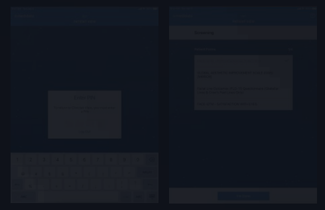

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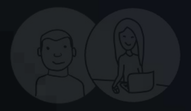

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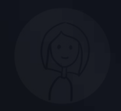
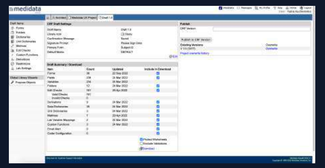


Patient

## STUDY START UP

### Designer



Replace Rave Architect. Manage SoA, trial forms etc…

CTMS, RSR, Study forecast, etc…

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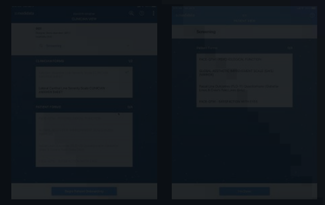

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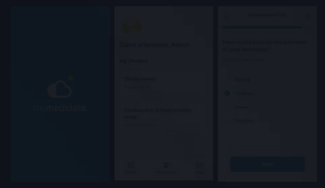

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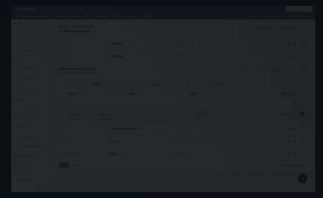

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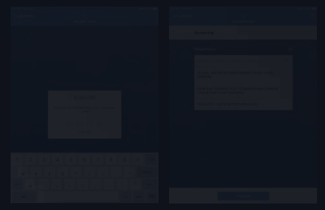

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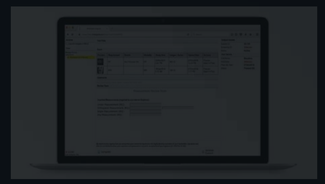

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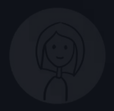

Patient

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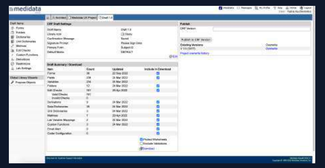

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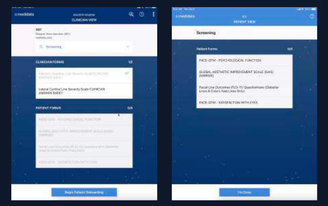

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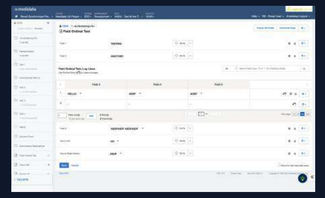

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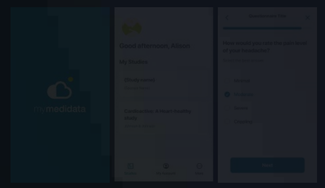

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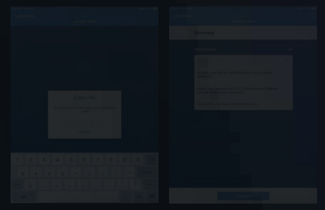

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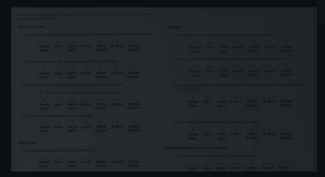

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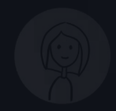

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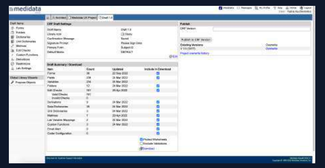

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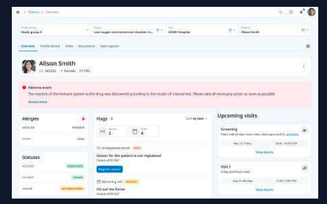
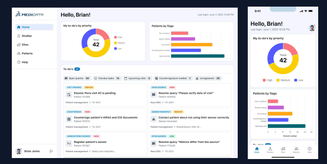


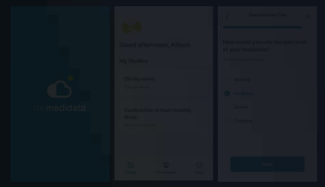
Web app

### Medidata app



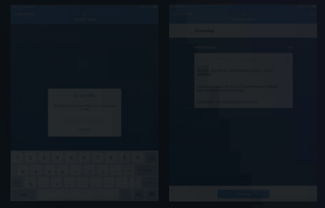
Tablet and smartphone companion app

### myMedidata



Smartphone app and web for PRO forms.

### Patient Cloud



Tablet app (available at a site only) for filling in PRO forms.

### Paper forms

Filling in paper forms at a site.

# 1X transformation path

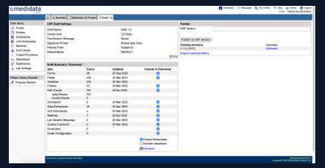
Study Builder, Data Manager

PI / CRC, Nurse, Other Site Staff

Patient

## STUDY START UP

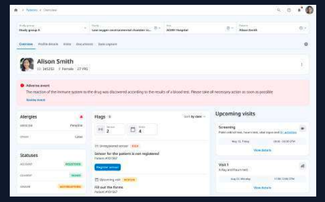
### Designer



Replace Rave Architect. Manage SoA, trial forms etc…

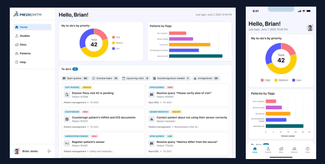
CTMS, RSR, Study forecast, etc…

### Patient management



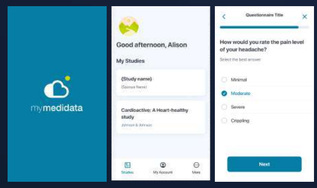
Web app

### Medidata app



Tablet and smartphone companion app

### myMedidata



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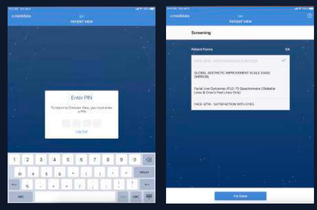
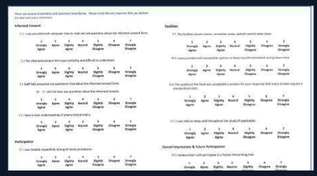
### Patient Cloud



Tablet app (available at a site only) for filling in PRO forms.

### Paper forms



Filling in paper forms at a site.

# 1X transformation path

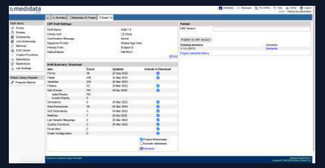
Study Builder, Data Manager

PI / CRC, Nurse, Other Site Staff

Patient

## STUDY START UP

### Designer



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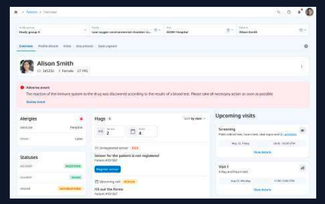
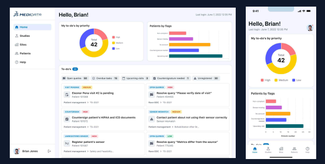
### Patient management



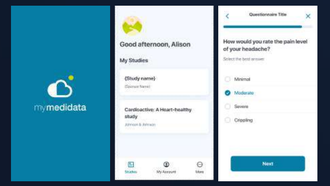
Web app

### Medidata app



Tablet and smartphone companion app

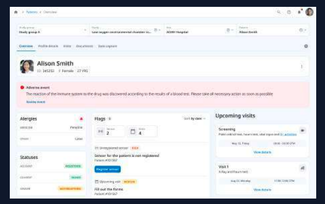
### myMedidata




Smartphone app and web: apply to study, sign consent, fill in forms, receive sensors etc.

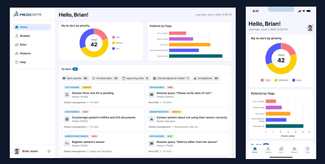
PI / CRC, Nurse, Other Site Staff

## Patient management



Web app

## Medidata app

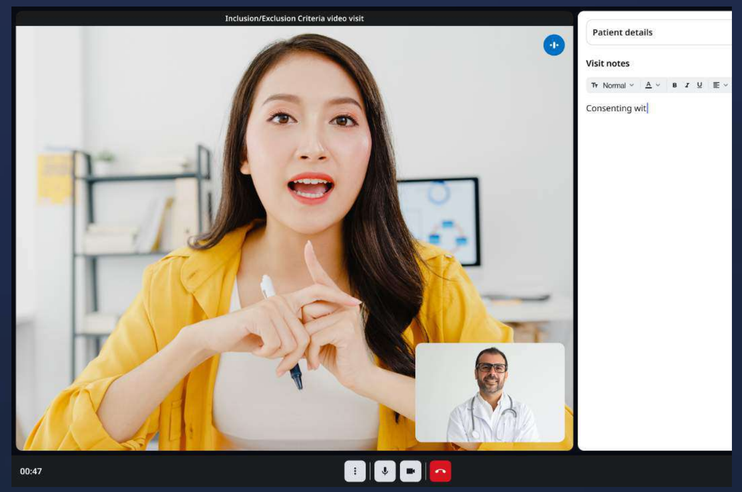


Tablet and smartphone companion app

# Things under design & development today

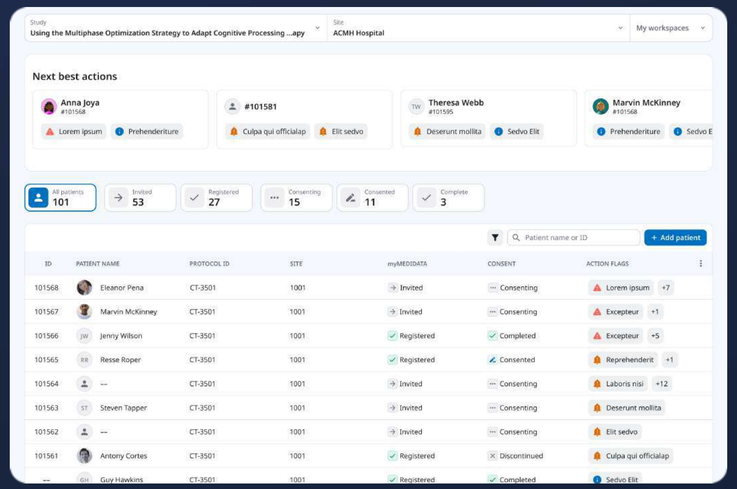
# Products in design & development today

## Medidata LIVE



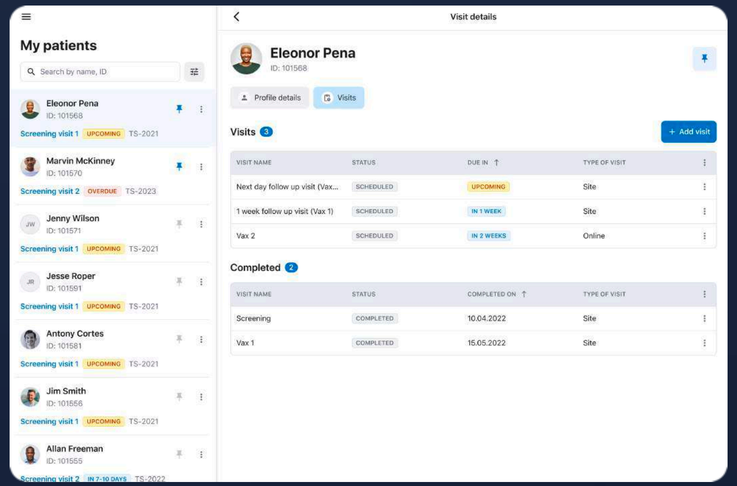

- Schedule and manage video visits between site staff and patients

## Patient Management



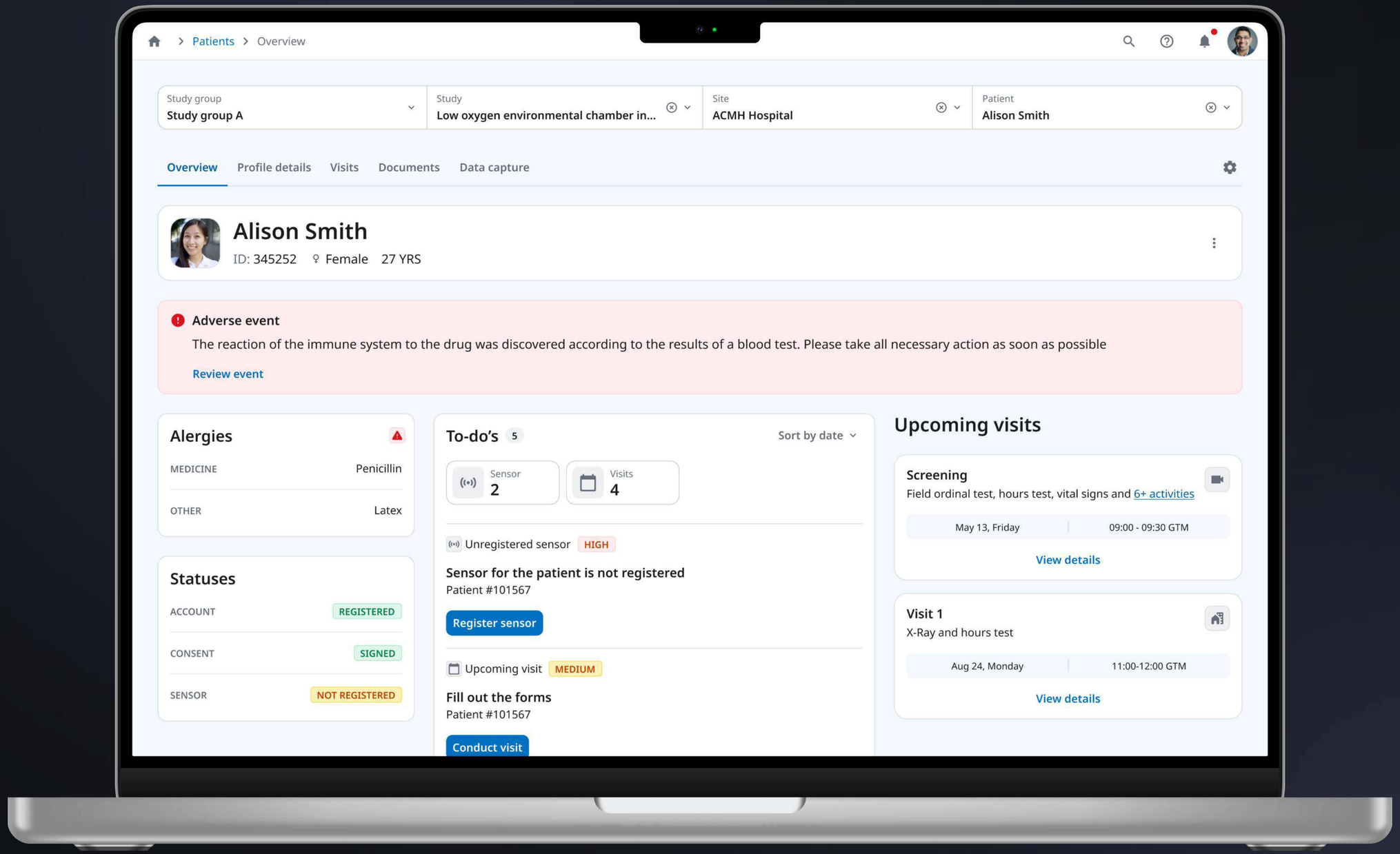

- Search patients and view patient profile
- Add patients to study
- Add paper consent form
- Countersign consent form
- Withdraw patient from study
- Manage sensors
- Activity log

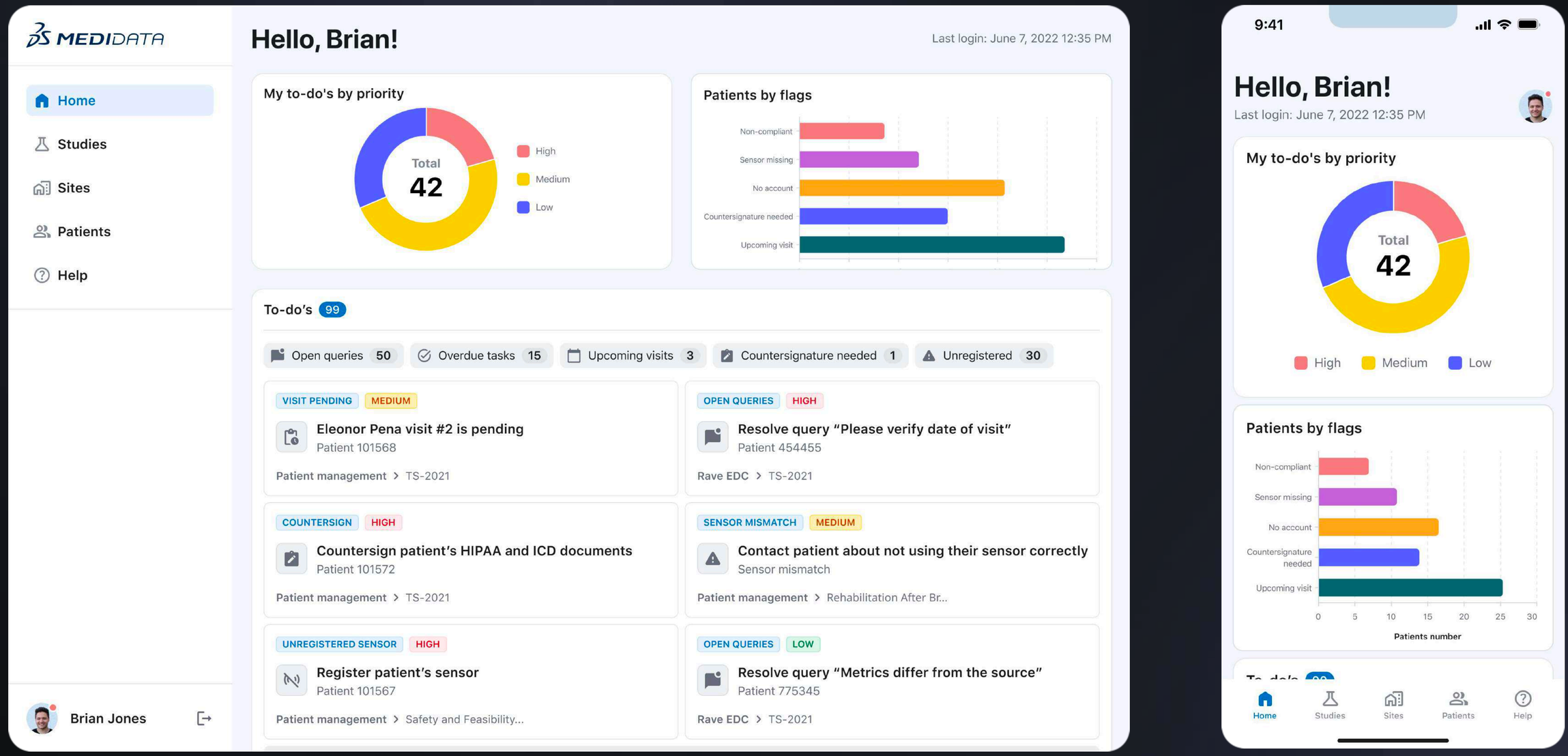
## Medidata App




- Manage and conduct patient visits and visit activities
- Fill in ClinRO forms
- Fill in PRO forms (on the CRC device)
- Plan unscheduled visits

# Future concept first iterations


Patients
Overview
Study group
Study group A
Study
Low oxygen environmental chamber in...
Site
ACMH Hospital
Patient
Alison Smith
Overview
Profile details
Visits
Documents
Data capture
Alison Smith
ID: 345252
Female
27 YRS
Adverse event
The reaction of the immune system to the drug was discovered according to the results of a blood test. Please take all necessary action as soon as possible
Review event
Alergies
MEDICINE
Penicillin
OTHER
Latex
Statuses
ACCOUNT
REGISTERED
CONSENT
SIGNED
SENSOR
NOT REGISTERED
To-do's
5
Sort by date
Sensor
2
Visits
4
Unregistered sensor
HIGH
Sensor for the patient is not registered
Patient #101567
Register sensor
Upcoming visit
MEDIUM
Fill out the forms
Patient #101567
Conduct visit
Upcoming visits
Screening
Field ordinal test, hours test, vital signs and 6+ activities
May 13, Friday
09:00 - 09:30 GTM
View details
Visit 1
X-Ray and hours test
Aug 24, Monday
11:00-12:00 GTM
View details


MEDIDATA
Home
Studies
Sites
Patients
Help
Brian Jones
Hello, Brian!
Last login: June 7, 2022 12:35 PM
My to-do's by priority
Total
42
High
Medium
Low
Patients by flags
Non-compliant
Sensor missing
No account
Countersignature needed
Upcoming visit
To-do's 99
Open queries 50
Overdue tasks 15
Upcoming visits 3
Countersignature needed 1
Unregistered 30
VISIT PENDING MEDIUM
Eleonor Pena visit #2 is pending
Patient 101568
Patient management > TS-2021
OPEN QUERIES HIGH
Resolve query "Please verify date of visit"
Patient 454455
Rave EDC > TS-2021
COUNTERSIGN HIGH
Countersign patient's HIPAA and ICD documents
Patient 101572
Patient management > TS-2021
SENSOR MISMATCH MEDIUM
Contact patient about not using their sensor correctly
Sensor mismatch
Patient management > Rehabilitation After Br...
UNREGISTERED SENSOR HIGH
Register patient's sensor
Patient 101567
Patient management > Safety and Feasibility...
OPEN QUERIES LOW
Resolve query "Metrics differ from the source"
Patient 775345
Rave EDC > TS-2021
9:41
Hello, Brian!
Last login: June 7, 2022 12:35 PM
My to-do's by priority
Total
42
High
Medium
Low
Patients by flags
Non-compliant
Sensor missing
No account
Countersignature needed
Upcoming visit
0
5
10
15
20
25
30
Patients number
Home
Studies
Sites
Patients
Help

# Conceptual design focus areas

# App design is built for 3 main visit locations and 4 personas

## Location

🏥 Site

🛏️ Bedsite (site)

🏠 Home

## User Persona

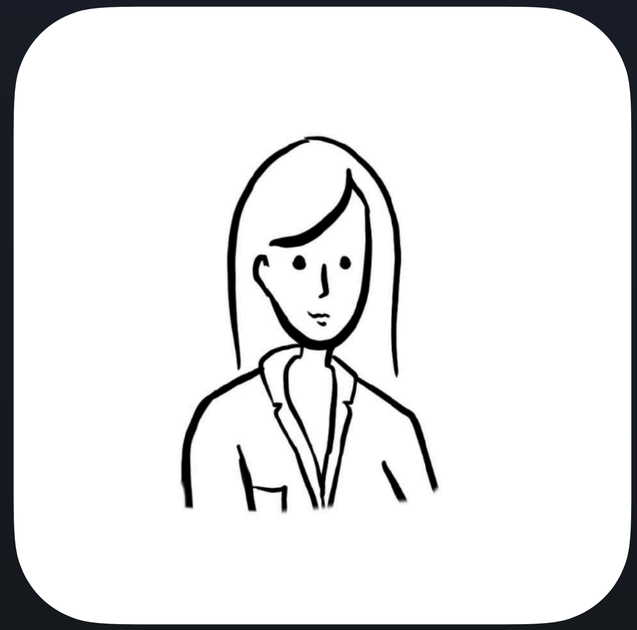
👩‍⚕️ Clinician

👩🏾‍⚕️ Nurse

📝 Rater

👨🏻‍⚕️ In-Home Health Nurse

# Site visit experience



Victoria

CRC

# Site visit experience (1/4)

Victoria checks her schedule upfront to find out what visits are planned for the next few days.

She looks through the activities needed for a patient visit to ensure everything is well prepared. List of activities is normally printed from the study protocol.

Victoria starts making preps before the visit, e.g. book X-Rey scan, CT, order ice for blood samples etc.

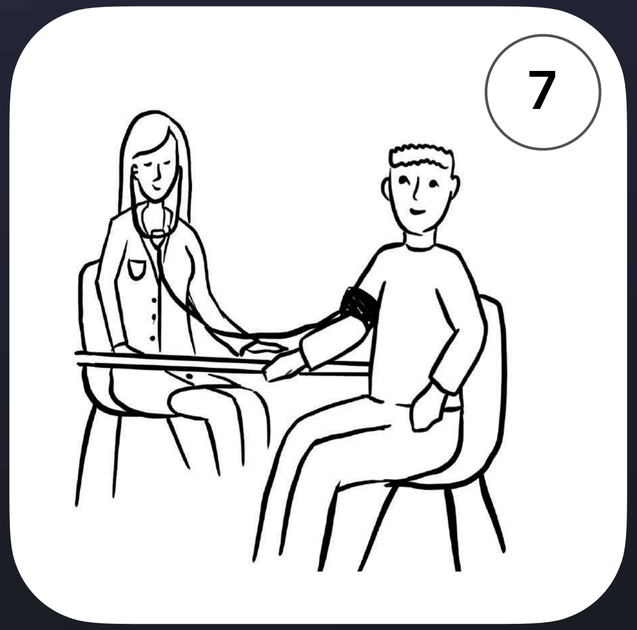
# Site visit experience (2/4)

Victoria calls the patient to ensure they are ready for the visit and reminds them on the preps needed.

Patient visits the site.

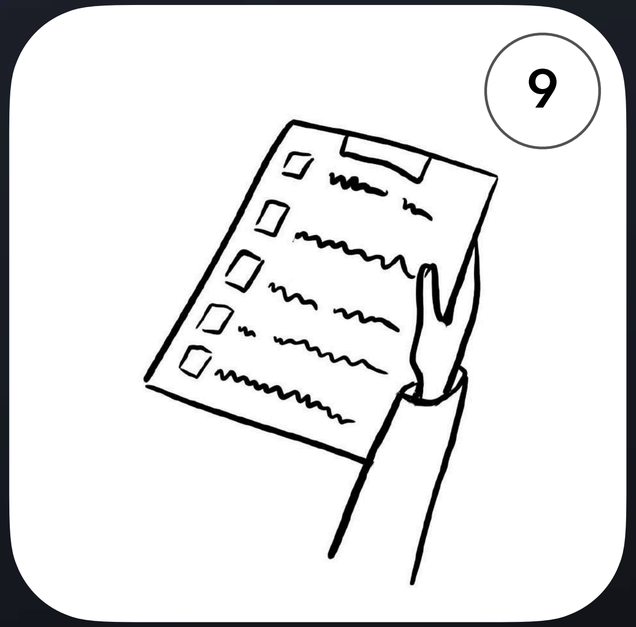
Patient meets with the clinician and site staff.

# Site visit experience (3/4)




Victoria checks for any adverse events since the previous visit and does the physical exam (regardless of protocol specifications).

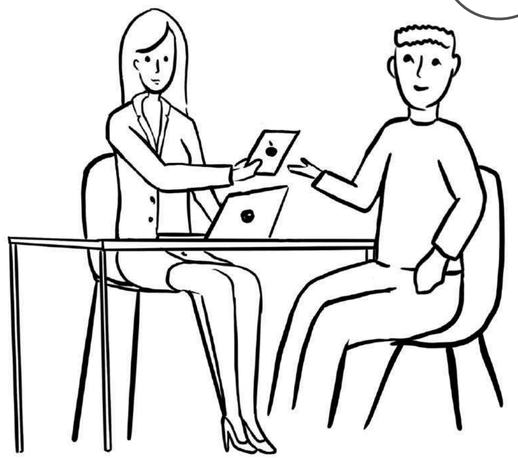
Clinician goes through the order of visit activities as specified in the study protocol.




Clinician goes through ClinRO forms required for the visit and enters data to the EDC system or into the paper forms.

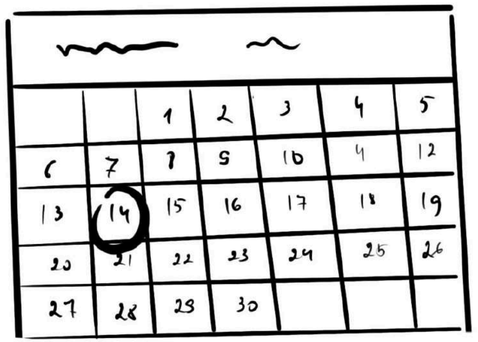
# Site visit experience (4/4)

10



Patient goes through the PRO forms by using the tablet provided by trial sponsor.

11



Clinician and patient agree on the date and time for the next scheduled visit.

12

Clinician or nurse receives the results of the tests and enters them to the EDC system.

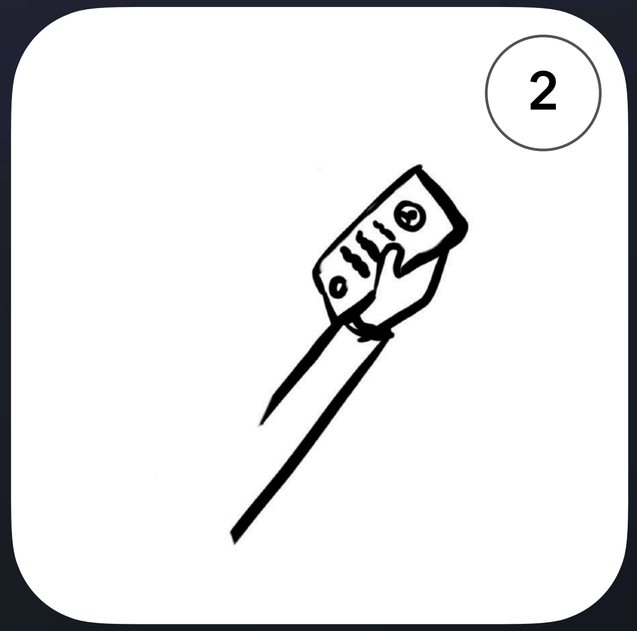
# Home visit experience

Peter

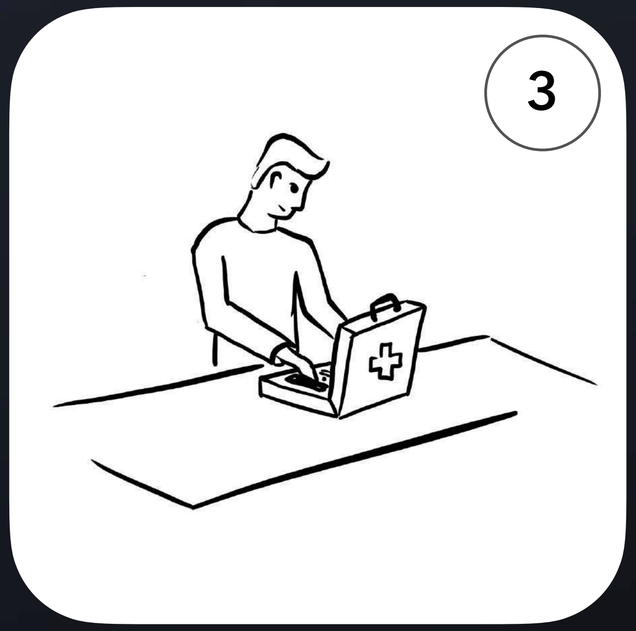
Home Health Nurse

# Home visit experience (1/4)

Peter is checking the ToDo list from the Medidata app. He has 3 patient visits scheduled for tomorrow.




Peter goes patient by patient and checks the required activities during the visit.




Peter ensures he has all the necessary equipment and things needed for the upcoming visits.

# Home visit experience (2/4)

4

Peter calls patients to confirm the time of the visit during the day.

5

When he gets to his car, he checks the patient address from the app and launches the nav app to help him get there. He also calls the patient again to inform about arrival time.

6

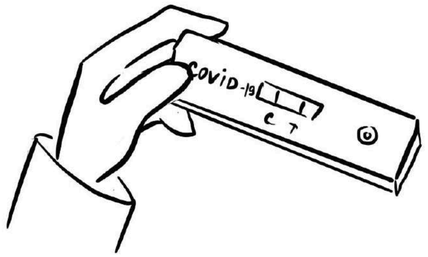
Peter arrives to the patient house.

# Home visit experience (3/4)

7

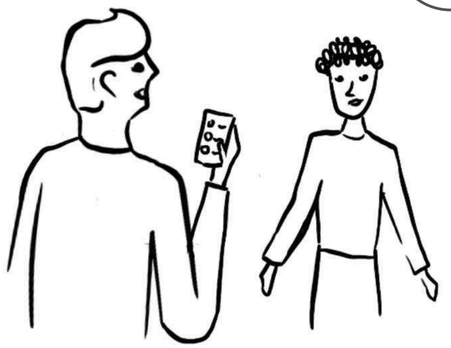
Peter meets the patient and walks them through the details of the visit and procedures.

8




Peter does the physical exam and other tests as needed during the visit as the first thing to do.

9



Peter launches the app to go through the required ClinRO and PRO forms during the visit.

# Home visit experience (4/4)

10

Once all activities are done, Peter completes the visit from the app.

11

Peter shares the details of the next steps with the patient and leaves the house. He informs the site about visit completion.

12

Peter opens the app and launches the address of the next patient. Usually he has 3-5 visits a day.

# User interviews key insights

# 4 interviews with 2 registered nurses and 1 PI (CRC)

## Margaret Shulman

- Registered nurse with 46 years of experience
- Visiting nurse for clinical trials in Jan - Jun 2021 in Massachusetts

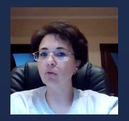
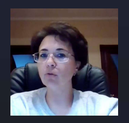
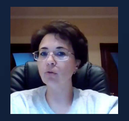
## Paisha Andersen

- Registered nurse with > 10 years of health experience
- Visiting nurse for clinical trials in Oct 2021-May 2022 in Washington state

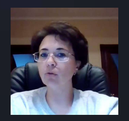
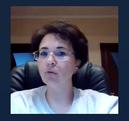
## Viktoriya Khomenko

- Clinician with 19 years of experience in conducting clinical research in Ukraine in many roles, including PI and rater
- Is a psychiatrist but has been involved in research for psychiatry, neurology, rheumatology and gastroenterology

# Interview highlights - concept (1/2)

| Interviewee | Problem | Solution |
|---|---|---|
|  | Upcoming visits schedule is a key data point that both the nurse and the PI/ Clinician use before and on the day of the visit. | Visits sorted by due dates. |
|  | Visit activities are used all the time, before and after the visit and are even carried around in paper form as a cheat sheet.<br><br>*" The best protocol is the one where visit activities are described in detail and are ordered. "* | Visit information includes the checklist of activities from the clinical protocol. |
| | It is not uncommon that paper forms are used but since the Covid-19 epidemic they are taken pictures of and uploaded to software. | Letting the clinician attach documents and photos to a visit / visit activity / digital form keeps documentation organized. |
| | It is crucial to know about patient's special medical conditions and chronic illnesses when preparing for the visit. | Allergies is an example of a field that can be included in brief patient info. |
|  | Patients ALWAYS forget their passwords/PINs. Calling the help desk to reset patient password takes too much time. | Security questions/OTPs are a secure and quick way to reset password/ PIN. |

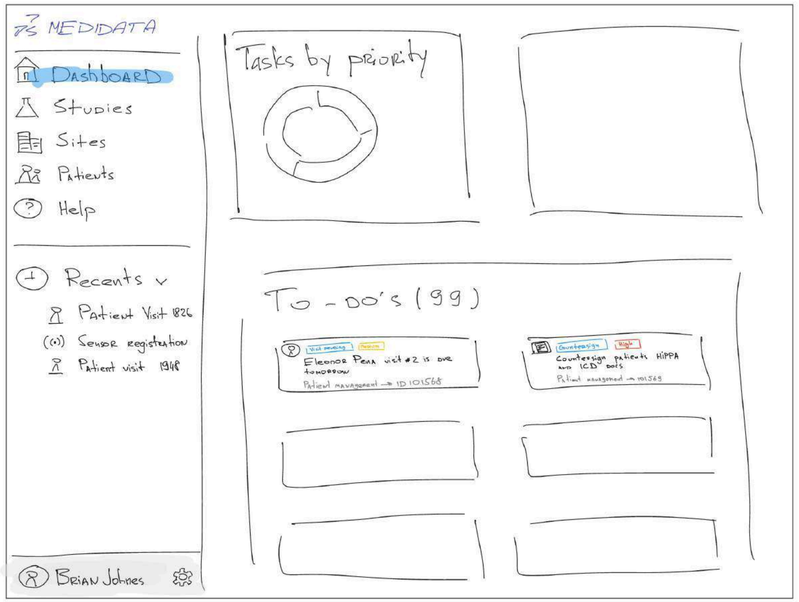
# Interview highlights - ideas (2/2)

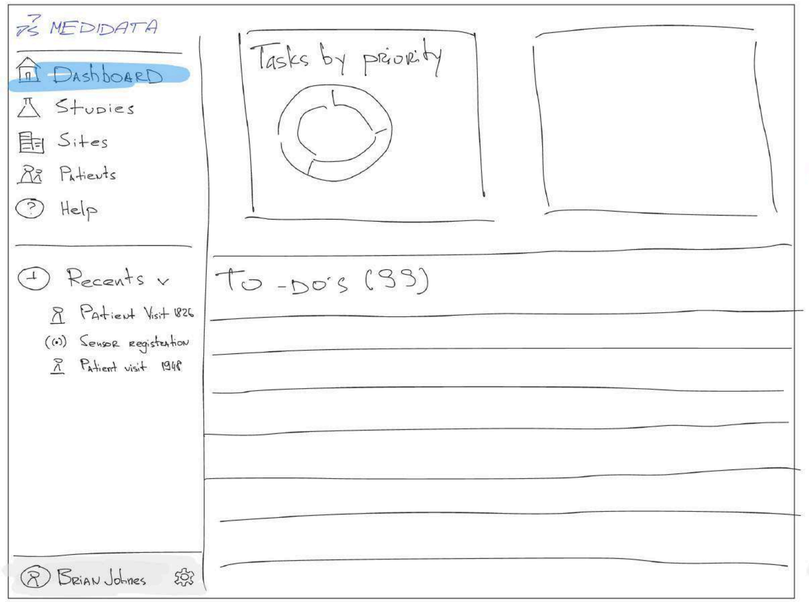
| Interviewee | Problem | Solution |
|---|---|---|
| | In case the clinician is managing organizational chores like ice ordering and delivery services, they rely solely on their memory / setting up reminders manually. | Notifications based on user personas / roles.<br>The PI might remember an administrative task while the nurse would be reminded to call the patient and prepare them for sampling. |
|  | Unscheduled visits are approved by the CRO individually due to budgeting and sponsor requirements. Approval process is done via email. | Unifying the entire job-to-be-done under one umbrella, eg recording an AE, creating a draft AE visit, getting CRO approval, scheduling and conducting the visit, all within 1 app. |
|  | It is the clinician's duty to teach the patient to use a device for PRO completion, even if they are afraid to use the technology or have no such experience. | Introducing patient / clinician onboarding to the app. |

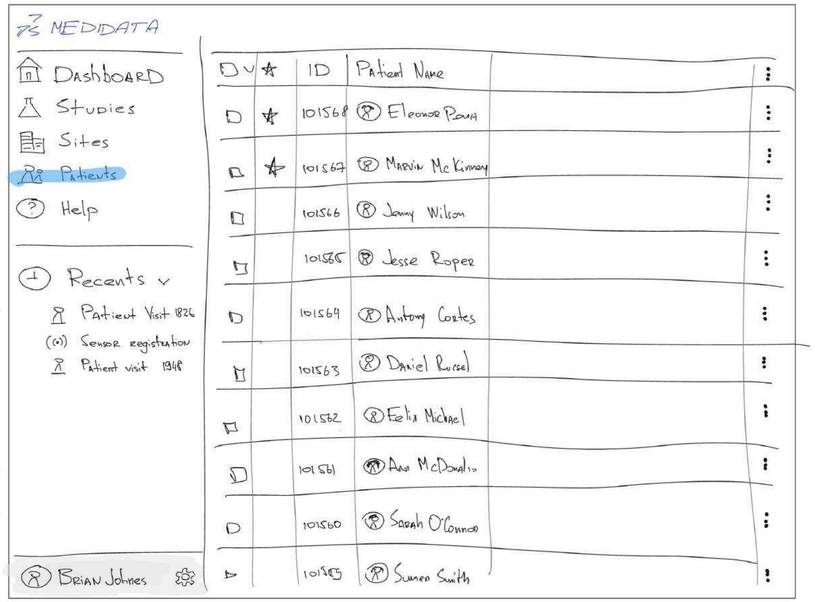
# Design Evolution

landing experience

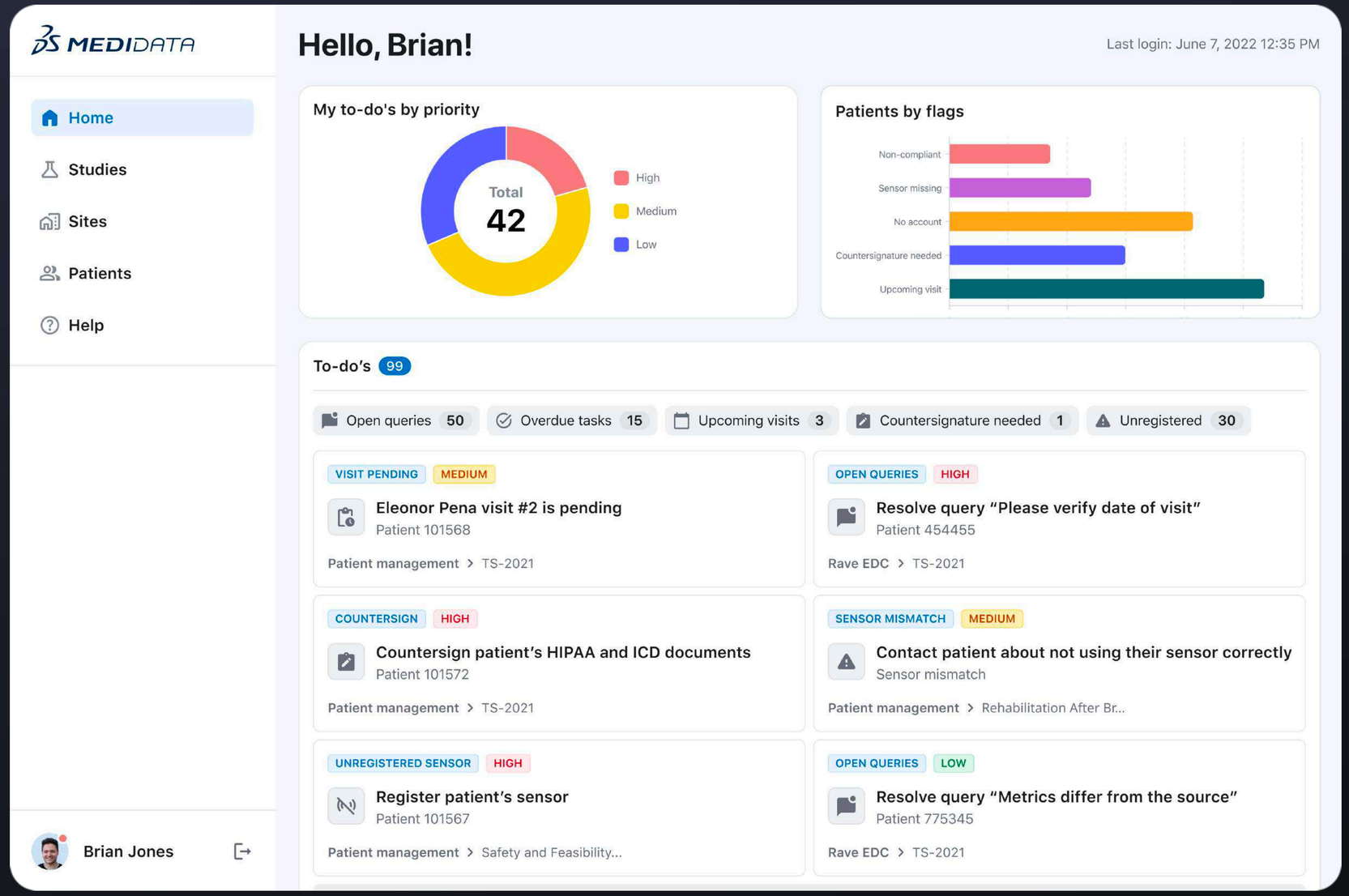
# Iteration 1: Exploring full platform potential

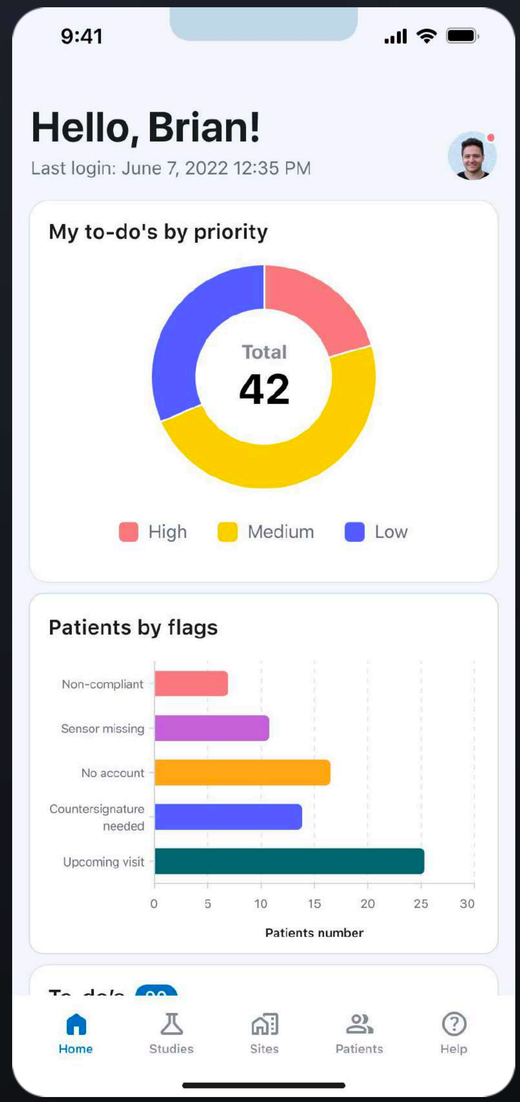


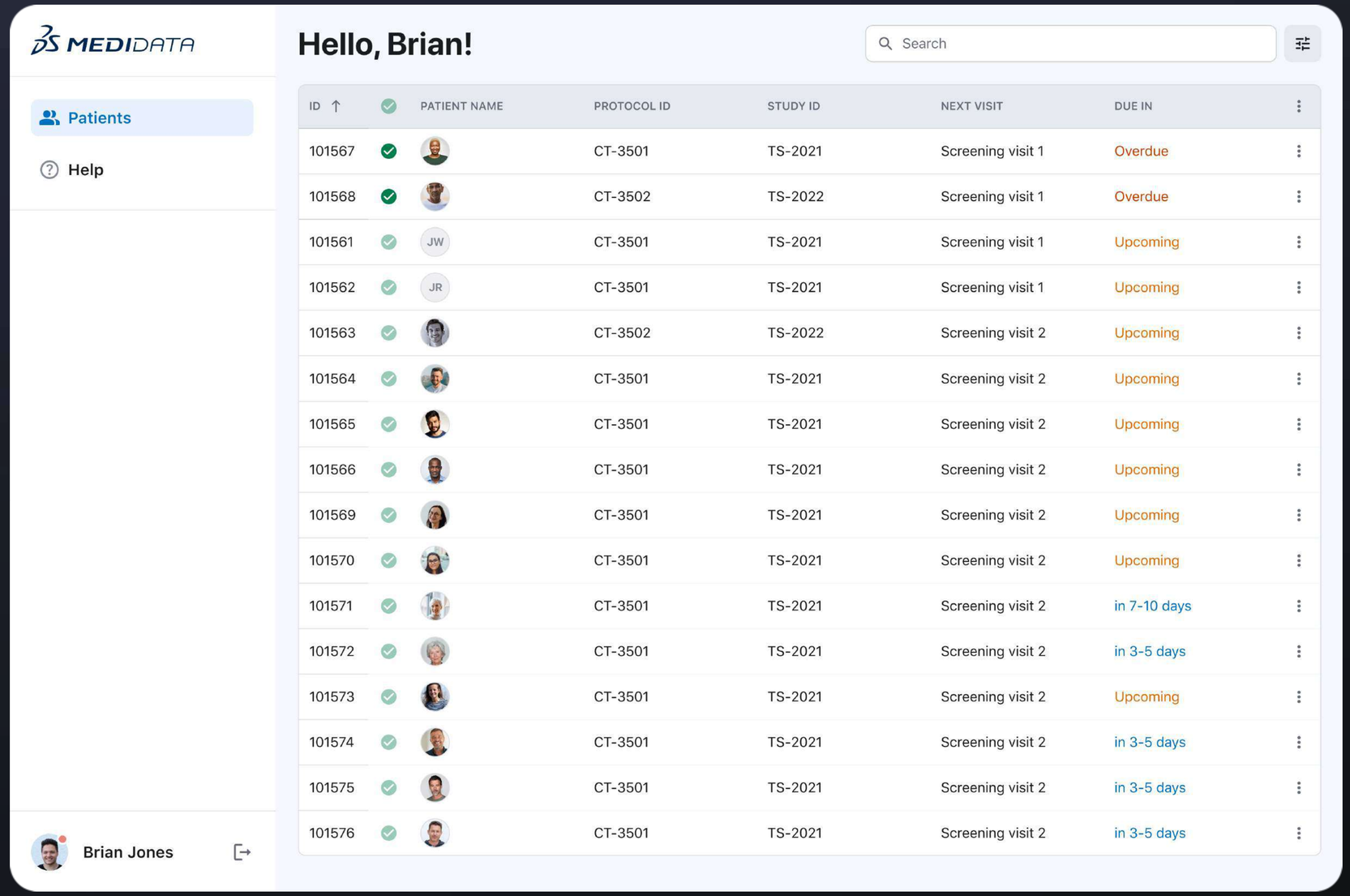



# Iteration 1: Exploring full platform potential

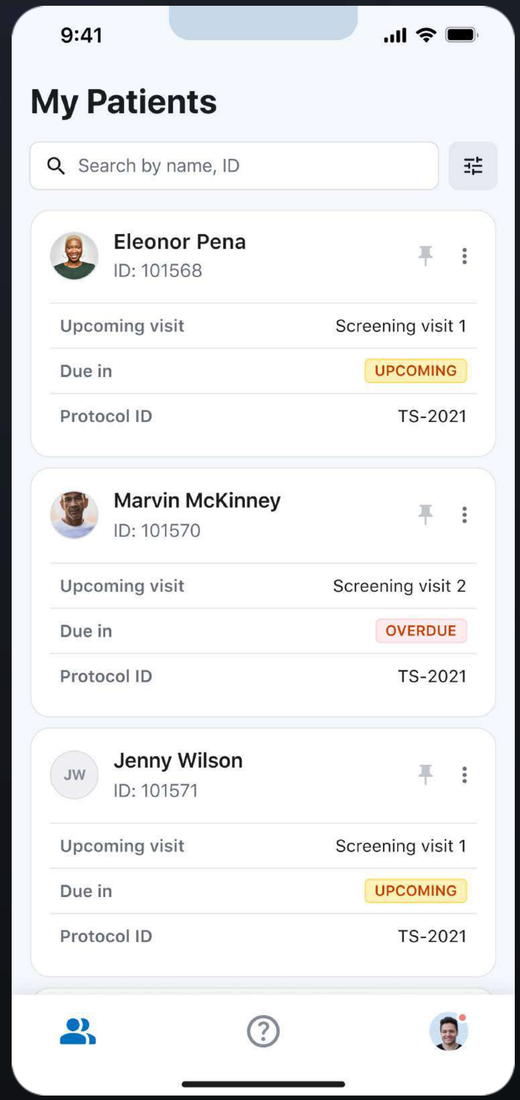
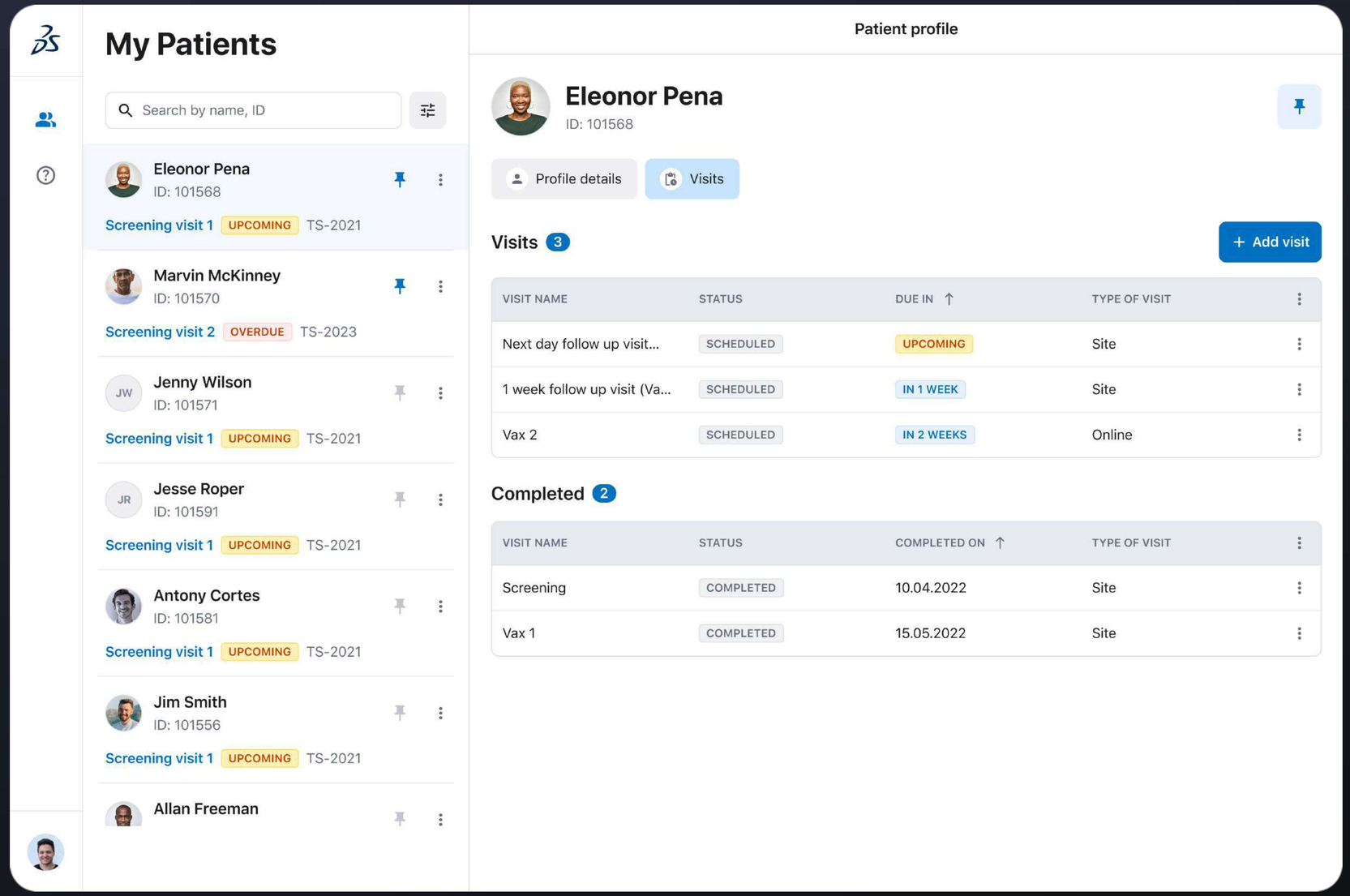
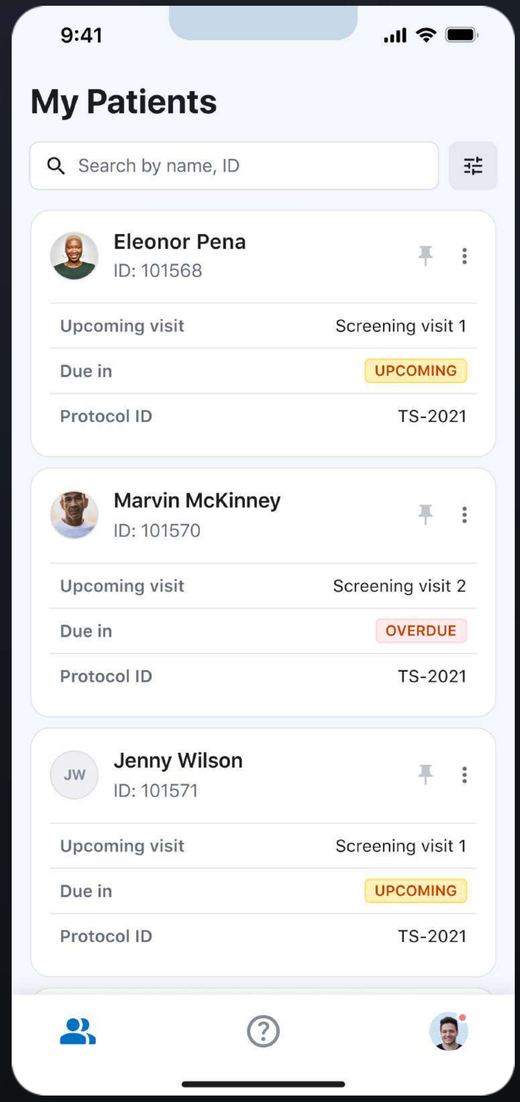


# Iteration 2: Focus on visit management




| ID | PATIENT NAME | PROTOCOL ID | STUDY ID | NEXT VISIT | DUE IN |
|---|---|---|---|---|---|
| 101567 | | CT-3501 | TS-2021 | Screening visit 1 | Overdue |
| 101568 | | CT-3502 | TS-2022 | Screening visit 1 | Overdue |
| 101561 | JW | CT-3501 | TS-2021 | Screening visit 1 | Upcoming |
| 101562 | JR | CT-3501 | TS-2021 | Screening visit 1 | Upcoming |
| 101563 | | CT-3502 | TS-2022 | Screening visit 2 | Upcoming |
| 101564 | | CT-3501 | TS-2021 | Screening visit 2 | Upcoming |
| 101565 | | CT-3501 | TS-2021 | Screening visit 2 | Upcoming |
| 101566 | | CT-3501 | TS-2021 | Screening visit 2 | Upcoming |
| 101569 | | CT-3501 | TS-2021 | Screening visit 2 | Upcoming |
| 101570 | | CT-3501 | TS-2021 | Screening visit 2 | Upcoming |
| 101571 | | CT-3501 | TS-2021 | Screening visit 2 | in 7-10 days |
| 101572 | | CT-3501 | TS-2021 | Screening visit 2 | in 3-5 days |
| 101573 | | CT-3501 | TS-2021 | Screening visit 2 | Upcoming |
| 101574 | | CT-3501 | TS-2021 | Screening visit 2 | in 3-5 days |
| 101575 | | CT-3501 | TS-2021 | Screening visit 2 | in 3-5 days |
| 101576 | | CT-3501 | TS-2021 | Screening visit 2 | in 3-5 days |



# Iteration 3: MVP further adjustments and simplification