MICHIGAN MEDICINE
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SleepSMART

Oct 11, 2021

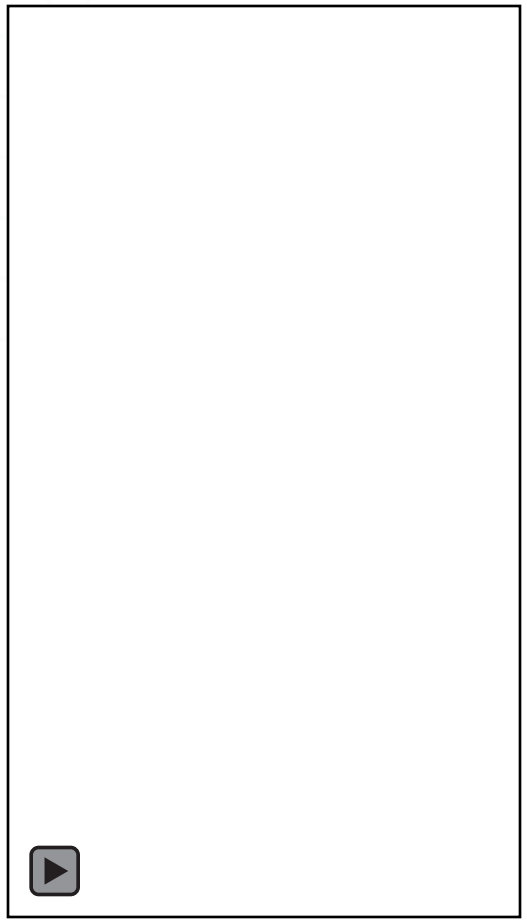
Overview

- Updates
- TikTok-style video contest winner announcement
- Data Management
- Primer on enrollment
- FusionHealth KOEO, T3, CPAP user guide

In the know….

- Sites released: 98
- Subjects consented: 1980
- Subjects randomized: 650

2nd place goes to University of Cincinnati!



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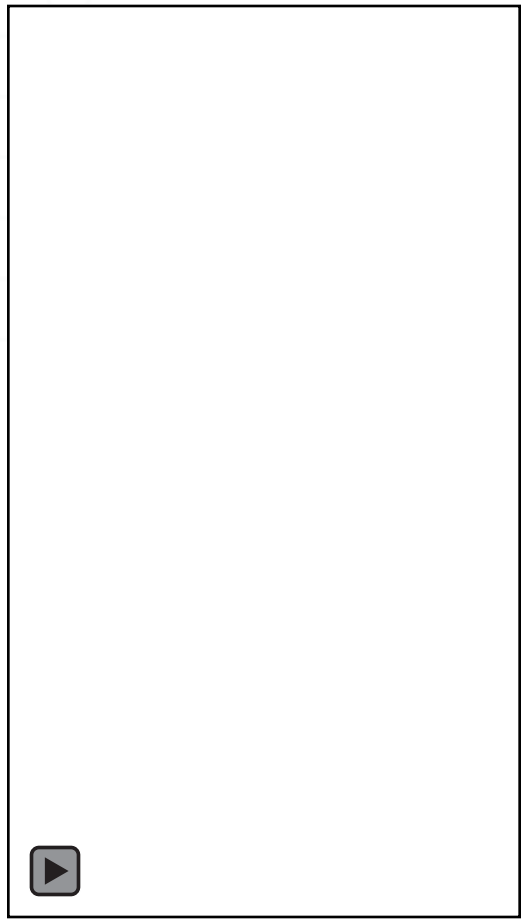
And the winner is……Baylor Scott & White!!



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Poll 1: For coordinators!

In Sleep SMART, what is your most common source of information for documentation of race and ethnicity?

1. I look at how race and ethnicity are documented in the medical record
2. I ask the participant what his/her race and ethnicity are
3. I document race and ethnicity based on my assessment after meeting the participant

Poll 2: For coordinators!

- In Sleep SMART, have you ever asked the participant his/her race?
  - Yes
  - No

Poll 3: For coordinators!

- In Sleep SMART, have you ever asked the participant his/her ethnicity?
- Yes
- No

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Data Management

- General Reminders
- Data Entry Reminders
- F504 Primary Outcome Report
- Data Collection Guidelines v5
- F245 Informed Consent
- F126 End of Study – PI Review/Signature
- Consenting and Monitoring

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Funded by a grant from the National Institutes of Health

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WebDCU General Reminders

- All CRFs must be completed
  - F104 Adverse Event is the only optional form.
- Please respond to all DCRs
  - Even if you have made the update on the form or emailed us, we still need you to respond to the DCR.
- All subjects must be moved to End of Study
  - Even those who are not randomized!
- Hospital Discharge Visit
  - If the subject was discharged before randomization, then post the Randomization visit first then post the Hospital Discharge visit and put the visit date as the same day as the randomization visit. Then in F123 Q01, you can add the correct date.

Data Entry Reminders

Please review your open rule violations to see if there are any that need to be addressed.

Common rule violations:

- Answering F101 A05 Protocol Version
- Answering F244 Informed Consent Version 4 Q10 and Q11
- Answering F245 Informed Consent Version 5 Q10 and Q11
- Answering F506 Q09 Run-in Night repeated

F504 Primary Outcomes Report

- Worsening of enrolling stroke should be included on F504 as these events need to be adjudicated

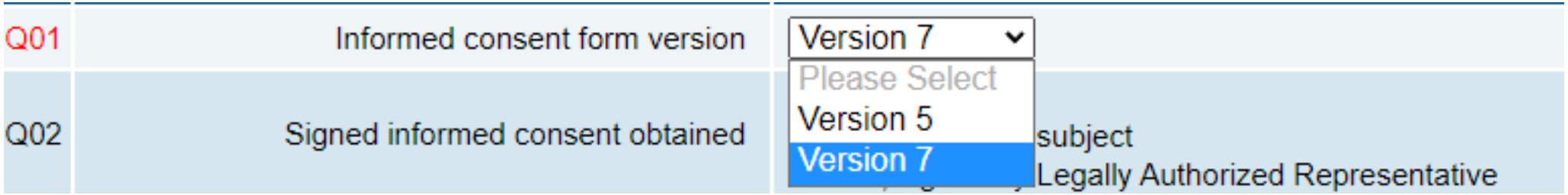
- Primary Outcome Event Packets must be de-identified and include:
  - ‘Event Packet Face page’ found in Project Documents
  - Narrative summary
  - 3 and 6 Month New Stroke or ACS Assessment Worksheets

Data Collection Guidelines v5

- There is a new Data Collection Guidelines v5
- Please make sure to download or print off this new version.

F245 Informed Consent

- Moving forward, we will no longer add a new CRF for each approved informed consent version. Instead, will collect the informed consent document on F245 regardless of the IC version number
- We have changed Q01 on the CRF to be a drop-down menu to include the various version of Informed consent.
- **If you have already uploaded a signed IC Version 7 document to F245 prior to this change, please go back and edit the CRF to update Q01 to 'Version 7'.**



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F126 End of Study – PI Review/Signature

- GCP Guidelines state: “The investigator should ensure the accuracy, completeness, legibility and timeliness of the data reported to the sponsor in the CRFs and in all required reports.”

- Updated guidance says “To comply with the requirement to maintain accurate case histories clinical investigator(s) should review and electronically sign the completed eCRF for each subject before the data are archived or submitted".

- So, compliance with the guidance would either be for a physical (wet ink) sign off of the CRF (for instance a free standing CRF PI's statement page – i.e. Form 126) or an electronic signature – which WebDCU does not currently have.

- **Therefore our current requirement for all DCU studies is that the site PI prints F126 and signs with a physical (wet ink) signature.** No note-to-files are allowed. *DocuSign is allowed*

Consenting and Monitoring Updates

- Informed Consent Form
  - Informed Consent Checklist is required to be uploaded along with ICF to WebDCU for review
  - If a NTF is requested, please remember to upload NTF along with ICF for review (in one upload)
  - Please make sure to respond to any open DCRs
- Monitoring visits (in process)
- Virtual site check-in meetings (in process)
- Site reports (Q3-2021)
  - Next reports will be circulated in late October

NDMC Contacts

Jocelyn Anderson - Data Manager
anderjoc@musc.edu

Faria Khattak - Data Manager
khattak@musc.edu

When to contact: User accounts, data entry, CRFs, or any other WebDCU-related questions

Katherine Trosclair – Site Monitoring Manager

trosclak@musc.edu

When to contact: If you have WebDCU-related DOA/regulatory database questions, Informed Consent, Remote or Site Monitoring questions

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A primer on enrollment

By Kayla Novitski

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Screening- Inclusion/Exclusion

Inclusion:

- Inpatient at an enrolling site
- ≥ 18 years old
- Ischemic stroke, or TIA with $ABCD^2 \geq 4$ within the prior 14 days

  (Although 14 days provides a wide window, we strongly encourage enrollment as soon as possible)

Screening- Inclusion/Exclusion

- **Exclusion Criteria:**
  - Pre-event inability to perform all of own basic ADLs
  - Unable to obtain informed consent from subject or legally authorized representative
  - Incarcerated
  - Known pregnancy
  - Current mechanical ventilation (can enroll later if this resolves) or tracheostomy
  - Current use of PAP, or use within one month prior to stroke
  - Anatomical or dermatologic anomaly that makes use of CPAP interface unfeasible
  - Severe bullous lung disease

Screening- Inclusion/Exclusion

- Prior or current spontaneous pneumothorax
- Hypotension requiring current treatment with pressors (can enroll later if this resolves)
- Other specific medical circumstances that could, in the opinion of the site PI, render the patient at risk of harm from use of CPAP
- Previous or current massive epistaxis
- Cranial surgery or head trauma within the past 6 months, with known or possible CSF leak or pneumocephalus
- Recent hemicraniectomy or suboccipital craniectomy (i.e. those whose bone has not yet been replaced), or any other recent bone removal procedure for relief of intracranial pressure
- Current receipt of O_2 supplementation >4 liters per minute
- Current contact, droplet, or respiratory/airborne precautions

Questions about eligibility?

Common question: I'm not a doctor! Who can help me determine if a patient is eligible? Answer: Your PI and/or local team.

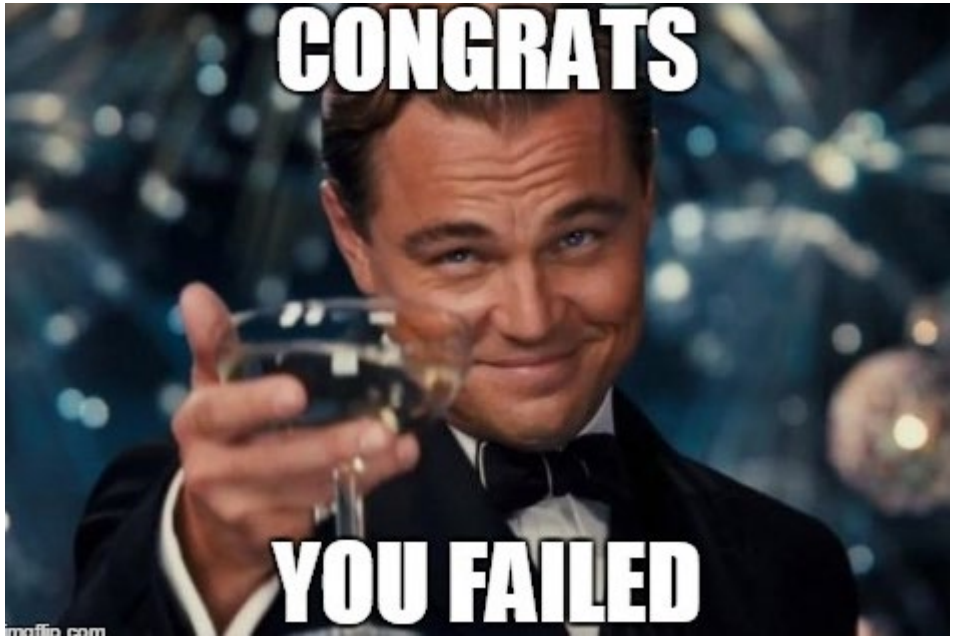
We are here to answer questions about interpretation of eligibility criteria by keeping tabs on the Sleep SMART Hotmail (it's Devin and Ron, sometimes Kayla)

Email: sleepsmart@umich.edu

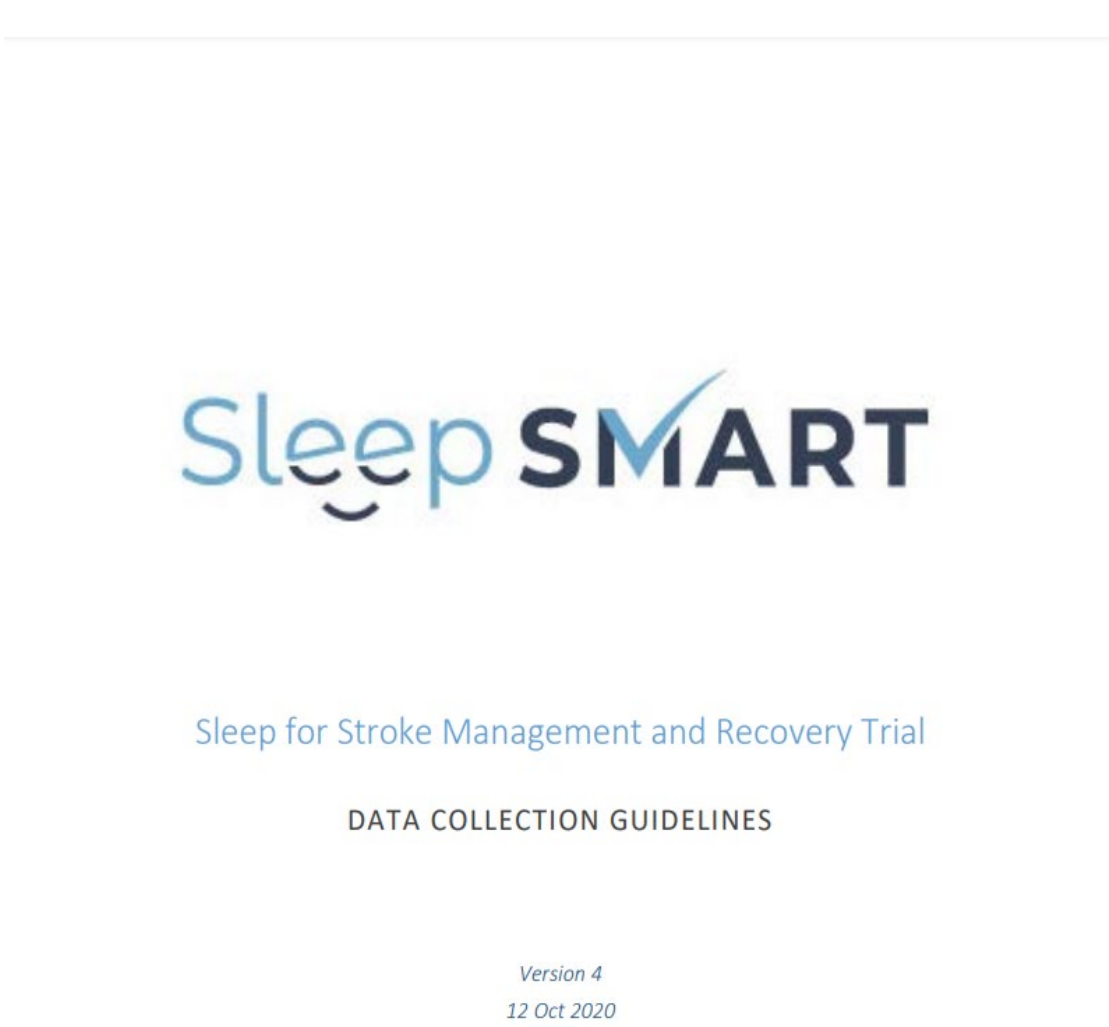
*remember no PHI in these emails

Screen Failures

- For Sleep SMART, you will document screen failures as any patient/LAR that was approached for consent but declined.
- You do not need to enter patients who do not meet eligibility
- Common question: Great, where do I put this information? Answer: In WebDCU under Study progress in the “screen failure” table. To add a subject, click on the “Add New” button on the top right hand side of the page.
- Is this information in a document? You betcha! Page 11 of the Data Collection Guidelines.



- Remember that Step by Step document we went over on the readiness call? No, here it is: https://www.nihstrokenet.org/docs/default-source/sleepsmart/documents/step-by-step-enrollment-checklist-30mar2021.pdf?sfvrsn=0
- Have this next to you when you enroll a subject, it will make your life 1000x easier. I promise!



- Don’t recognize this either? You should! This is the Sleep SMART Data Collection Guidelines.
- I will reference this document a lot!
- If you haven’t printed this out, please do. Print an extra copy for your bedside table.

Screening- I think I found an eligible patient, what next?

- Great! It's time to approach the patient. Not sure what to say? We have a script for that! The script can be found in the WebDCU toolbox. If you can't locate a document, just reach out to Joelle or Kayla. We would be happy to send you any documents
- After introducing the study, you'll want to show the recruitment video, then have the consent conversation, and remember to use the mandatory informed consent checklist
  - Recruitment video link: https://drive.google.com/file/d/1_PM1UclbzK7lz9AH25C8wywYv3nfT6Zf/view
  - Consent Checklist: https://www.nihstrokenet.org/docs/default-source/sleepsmart/research-team/informed-consent-process-checklist_06jan2020.pdf?sfvrsn=0

Adding a new subject

- Congrats you consented a subject! Now he/she will need to be entered into WebDCU
- To add a new subject into WebDCU:
  - A: Select [Add new subject] on the home screen.
  - B: If you have permissions at more than one site, select the appropriate site from the “site” drop-down box.
  - C: complete all items on the form and click [Save record]
- Is this information in a document? In the WebDCU toolbox, titled *“ Sleep SMART Enrollment and Randomization Instructions”*

Medicare ID (MBI)

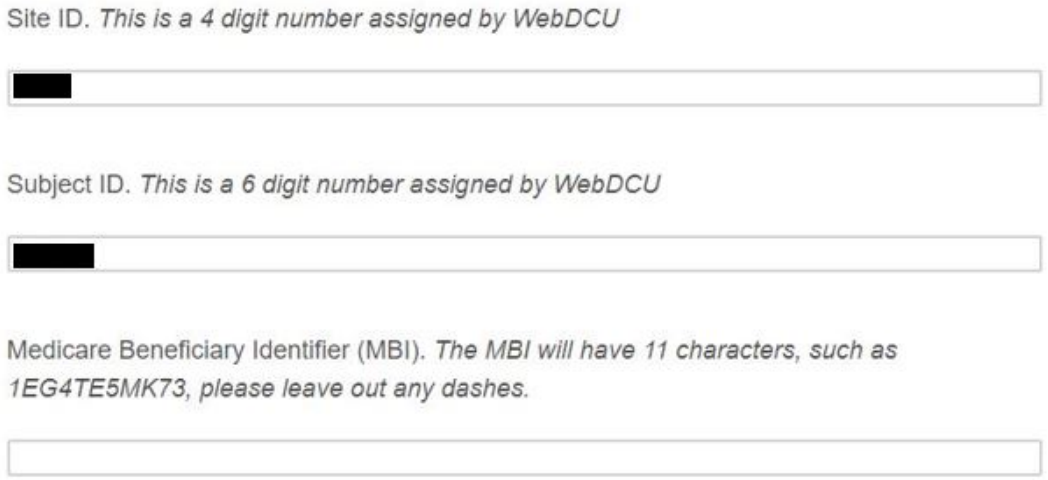
- When you “add a new subject” in WebDCU, the subject enrollment form opens automatically. On the form, is where the Medicare ID question is. If a subject does have one, the green arrow will link to where you need to fill it out. This is in Qualtrics.

Q10	Subject covered by Medicare *This includes Medicare Part A and/or Part B.*	No Yes Unknown
Q11	Medicare Beneficiary ID is available *The Medicare Beneficiary ID is an 11 character ID such as 1EG4TE5MK73. This should be found in the medical records.*	No Yes
Q12	Link	https://umich.qualtrics.com/jfe/form/SV_8FVrOtsXae9Pbi5? &Q_PopulateResponse=%7b%22QID8%22:%221517%22,%22QID7%22:%22100004%22%7d

Medicare ID (MBI)

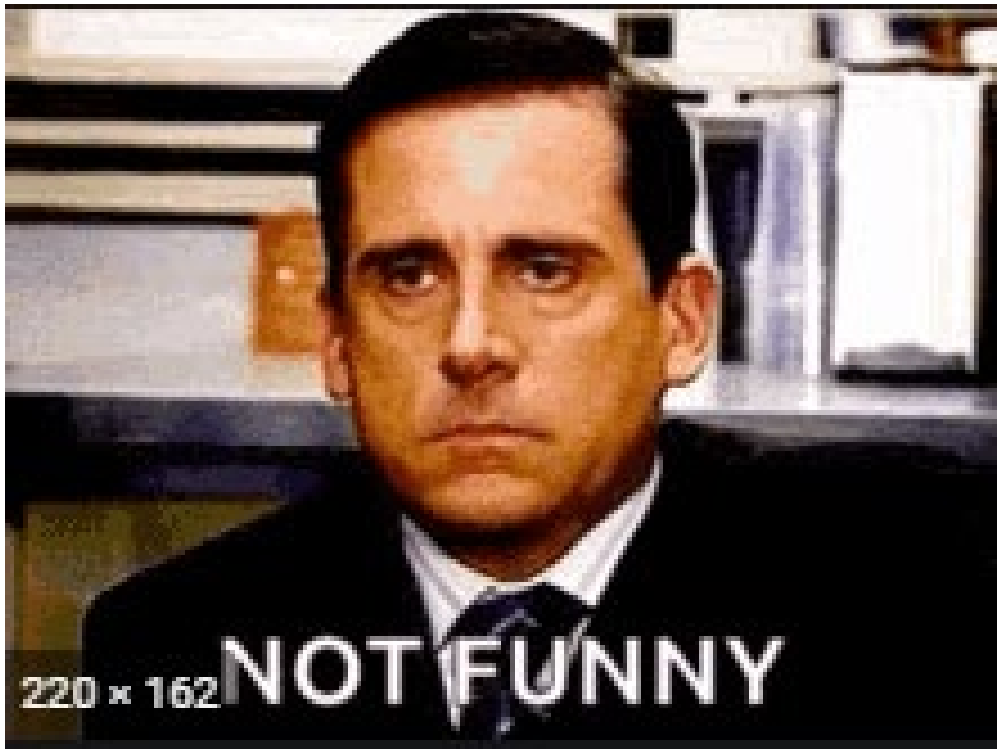
- 11-digit mix of letters/numbers that looks like this:
  - 1EG4-TE5-MK73 [correct]

- Not a SSN followed by a letter at the end:
  - 000-00-0000b [incorrect]



Fun Facts

- WebDCU and KOEO do **NOT** speak to each other
- Anytime a new subject is added, Kayla or Devin will respond to the automated New Subject Email with detailed instructions on what to add in KOEO



Baseline data

- You added your subject in WebDCU, you should now have a 6-digit subject ID. This ID will need to be entered into KOEO.
- It's time to collect baseline data.
- Common questions: Where are the baseline data forms? Do I need to make all the CRFs myself? What is a CRF? Answers: They are in WebDCU under the Project Setup tab, please do not make them yourself! We have them available to print as an entire visit or individually. CRF stands for Case Report Form.
- Please collect baseline data as soon as you have consent
- Baseline data must be collected even for those who don't get randomized

Where are the CRF's??

- In WebDCU, click on the Project Setup Tab -> CRF Collection Schedule

WebDCU | Sleep SMART

Kayla NOVITSKI Sign Out

Help

CRF Collection Schedule

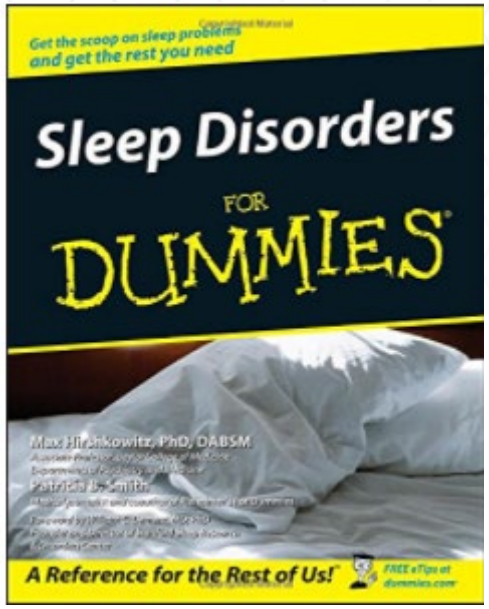
CRF Name	Baseline	Randomization	Hospital Discharge	3 Month	6 Month	End of Study
F101 Eligibility	X M					
F102 Randomization		X M				
F104 Adverse Event	O R M	O R M	O R M	O R M	O R M	
F106 Medical History	X M					
F117 Vital Signs	X M					
F123 Hospital Discharge			X M			
F126 End of Study						X M
F139 HADS - D	X			X	X	
F143 NIH Stroke Scale	X M			X M	X M	
F144 Modifed Rankin Scale	X					
F151 Short SSQOL				X M	X M	
F167 Short MoCA				X M	X M	
F202 IQCODE	X					
F209 Clinical Management and Medication Adherence				X M	X M	
F241 Epworth Sleepiness Scale	X			X	X	
F244 Informed Consent Version 4	X M C					
F245 Informed Consent Version 5		X M C				
F255 PROMIS - Global Health				X	X	
F290 10 Meter Walk Test				X M		
F291 ABCD^2 Score	X M					
F292 Modified Rankin Scale 9Q				X M	X M	
F309 COVID-19 Assessment		X				X C
F501 STOP - BANG	X					
F502 Sleep Duration Questionnaire				X	X	
F503 Blood Pressure Follow-Up				X M	X M	
F504 Primary Outcomes Report						X M C
F505 CPAP Follow-Up Questionnaire						X M C
F506 aCPAP Run-In Night	X M					

X: Required O: Optional R: Repeatable M: Monitor Verify Required C: Conditional

More documents?! Are you serious!?

- Don’t try to start Night 1 without having the FusionHealth MOPs printed. Seriously, you will never get it right if you are “winging it.”
- There are 6 FusionHealth MOPs to get you through using the T3, KOEO, Mask fitting, and the CPAP run in night. **They give detailed step by step instructions on how to do everything! Print these and have them handy during this process**
- Where are they located? https://www.nihstrokenet.org/sleep-smart-trial/research-team under the Nox T3 and Run In Night tab

The dummy T3 test



- Sites are only required to do 1 dummy T3 test before they enroll their first subject.
- However, if you are new and want to do a dummy test just reach out to Kayla or sleepsmarttechsupport@noxhealth.com for instruction.
- A dummy test is a great way for you to become comfortable using the T3 before you use it on an actual subject.

FusionHealth training videos

- We have training videos for the Nox T3, Mask fit, and aCPAP.
- Guest starring Helgi and his father- do not miss these!
- Where do I find these? Under the Nox T3 and Run In Night Tab https://www.nihstrokenet.org/sleep-smart-trial/research-team

Night 1, the Nox T3 Night

- Remember those 6 FusionHealth MOPs I just told you to print? Open up the one that is titled *"configuring a Nox T3 sleep apnea testing device in KOEO"*
- Get the device ready- connect the T3 to a computer and configure the device. If you run into technical problems or have questions, phone 404-480-5149 ext 4006 or email sleepsmarttechsupport@noxhealth.com
- Once set up, apply the T3 to the subject and start recording prior to anticipated sleep
- Next morning you will download the Nox T3 data into KOEO
- Common question: Does the T3 need to be applied on Night 1? Answer: Ideally, but we give a longer window if needed. The window is stated on page 48 of the Sleep SMART MOP

Night 1, the Nox T3 Night, continued

- Once you have downloaded the data into KOEO, the data will need to be scored by the scoring team. Scoring times are at 10am/2pm ET
- You will be waiting to receive an email that the T3 has been processed. Once its processed, you will login into KOEO to see the results.
- If the subject is eligible based on their T3 results, you will go onto the CPAP Run In Night
- If the subject is NOT eligible for the run in night, you will print the Nox T3 report for the subject and clinical team and move them to End of Study in WebDCU.

The mask fitting

- During the day, complete the mask fitting for the subject. If you are working with an RT or sleep tech, they are experts at this- get their help.
- If you do not have RT or sleep tech help, we have created training videos: https://www.youtube.com/watch?v=dz3AD5aWlpA.
- Is this information in a document? Yes, the MOP that is titled *"Mask fitting MOP"*

Night 2, the CPAP Run In Night

- Open up the MOP titled *"Run-In Night Instructions"*
- Have the subject practice placing and removing the mask many times
- Have the subject use CPAP while awake for 15-20 minutes so they can get used to it before bedtime
- Apply CPAP overnight for 1 night to determine randomization eligibility
  - Have RT check on subject during the night and troubleshoot any issues
  - Document CPAP results (read directly from the device) and enter into WebDCU
- Randomization criteria:
  - Used aCPAP for ≥4.0 hours (read off device)
  - aCPAP CAI <10 (read off device)
  - Subject willingness to continue with Sleep SMART (must ask subject)

If eligible to randomize:

- If a subject is eligible for randomization, the randomization visit should be completed. To complete, in the [Subject CRF Binder] select ‘Add New Visit’ and choose ‘Randomization’ from the drop down menu
- Complete F102 Randomization, select [Save Record] and then the [Submit CRF] button.
- Is this information in a document? In the WebDCU toolbox, titled *“ Sleep SMART Enrollment and Randomization Instructions”*
- Once randomized, you will again receive a message from Kayla or Devin with information on what to do if the subject is randomized to the control or intervention group.
- Please go into KOEO and give the randomization assignment. Remember that KOEO and WebDCU do not speak, so you need to let FusionHealth know what the subject was randomized to. If your subject randomized to Intervention (CPAP), you will need to enter PHI at this point into KOEO.

If **not** eligible to randomize

- Print off the Nox T3 results from KOEO and provide to the participant.
- Move the patient to End of Study in WebDCU
- Participation is now complete

Are we done yet?

- Sorry, no.

Randomization assignments

- If subject is randomized to **control (no CPAP):**
  - Use script to describe randomization assignment
  - Schedule the 3 month visit before discharge
  - Provide Stroke symptom recognition handout

If subject is randomized to **Intervention (CPAP):**

- Use script to describe randomization assignment (will remind you about myAir and the care management video)
- Provide a new aCPAP device for use during the remainder of the hospitalization and after discharge (set aside the run-in night device for the next opportunity), provide the masks, humidifier basin, and tubing from the run-in night as extra supplies, and provide the stroke symptom recognition handout.
- Schedule the 3 month visit before discharge
- Begin nightly CPAP use with overnight support from RT or sleep tech
- Have RT/sleep tech provide CPAP education to subject and caregiver/bedpartner
- Play care management video for subject/caregiver
- Offer to help program the Care Team (Sleep Coach) phone number (470-655-6688) into the subject's cell phone and help initiate the first call with Fusion.
- Remind subject that if another call is completed with the Sleep Coach within the first week of discharge from the current hospitalization, he/she will be eligible for a $10 amazon gift card.
- If discharged to location other than home, provide CPAP order.
- When the subject is discharged from the hospital, please call the Care Team (470-655-6688) to let them know.

Month 3 and 6 visits

- Remember these are **blinded** visits!
- Can be done in person or by phone. **Cannot** be completed via video.
- For a list of what assessments can be done by phone and by proxy, please use the document "3 and 6 Month Assessment Guide" in the WebDCU Toolbox
- Common question: Does my blinded assessor need to be added to the DOA? Answer: Yes!

SleepSMART

3 and 6 Month Assessments Guide

Assessments that can be done via proxy

- F151 Short SSQOL
- F241 Epworth Sleepiness Scale
- F292 Modified Rankin Scale - 9Q
- F502 Sleep Duration Questionnaire
- 3 and 6 Month New Stroke and ACS Assessment

Assessments that can be done via telephone

- F139 HADS-D
- F151 Short SSQOL
- F167 Short MoCA
- F209 Clinical Management and Medication Adherence
- F241 Epworth Sleepiness Scale
- F255 PROMIS Global Health
- F292 Modified Rankin Scale - 9Q
- F502 Sleep Duration Questionnaire
- 3 and 6 Month New Stroke and ACS Assessment

If an assessment is not done or cannot be done due to the type of visit, or who is answering the questions, then you will need to still complete the form in WebDCU and indicate in the general comments a short explanation as to why this was not able to be done.

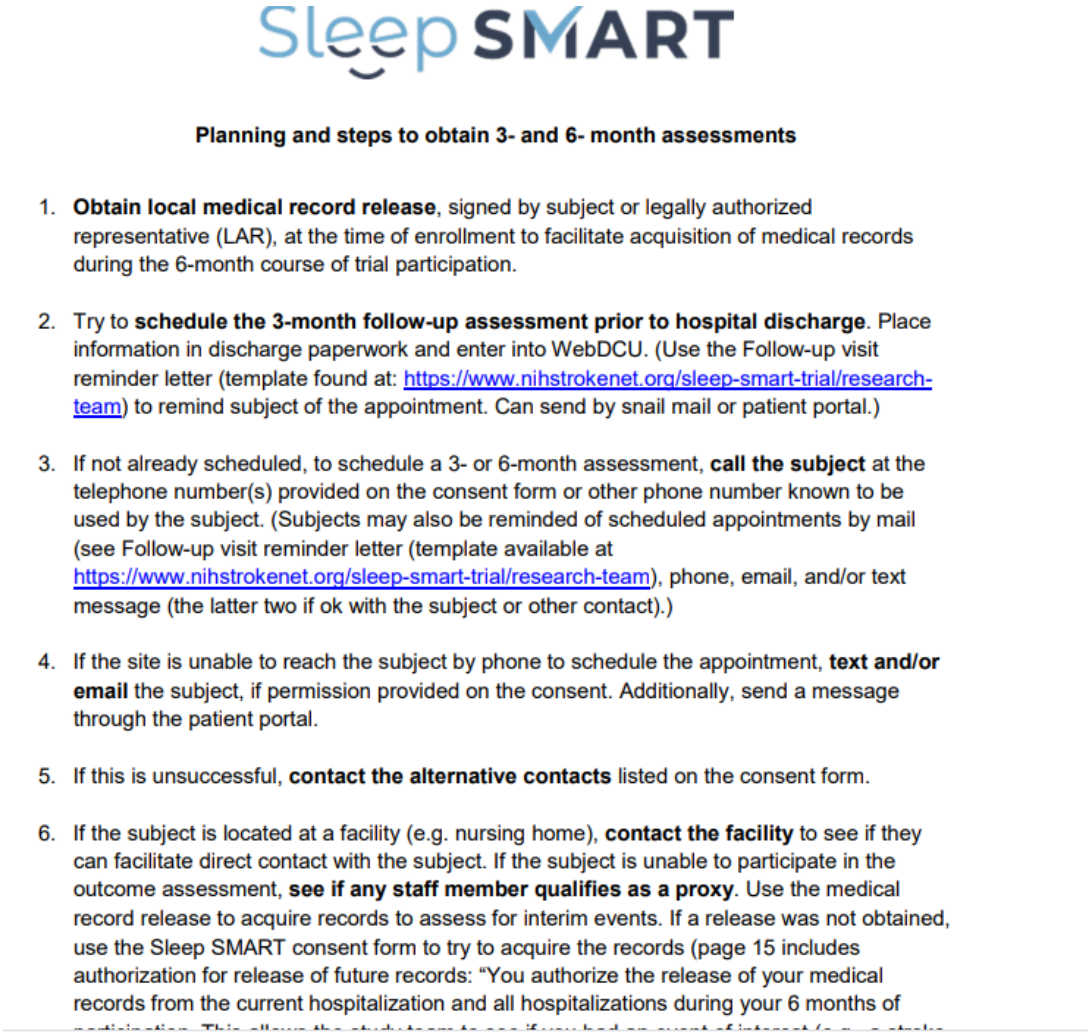
- This is the 3- and 6-month assessment guide I mention on the previous slide

3 and 6 month visits continued

- The **3 month** visit window is -30 days/+30 days from randomization
- The **6 month** visit window is -14 days/+60 days from randomization
- There is a study calendar in WebDCU under the Study Progress Tab. You can use this module to track both the visits already posted and projected visits

Tips for reaching subjects for their visits

- See the document "Steps for obtaining the 3- and 6-month visit" for a hierarchy of how to reach subjects. Found in WebDCU under Toolbox
- We have created tools to help you reach subjects that include, all included on our website under the Staff Documents tab https://www.nihstrokenet.org/sleep-smart-trial/research-team:
  - Follow up visit reminder letter
  - Unable to reach letter
  - Lost to follow up letter



Sleep SMART

Planning and steps to obtain 3- and 6- month assessments

1. **Obtain local medical record release**, signed by subject or legally authorized representative (LAR), at the time of enrollment to facilitate acquisition of medical records during the 6-month course of trial participation.

2. Try to **schedule the 3-month follow-up assessment prior to hospital discharge**. Place information in discharge paperwork and enter into WebDCU. (Use the Follow-up visit reminder letter (template found at: https://www.nihstrokenet.org/sleep-smart-trial/research-team) to remind subject of the appointment. Can send by snail mail or patient portal.)

3. If not already scheduled, to schedule a 3- or 6-month assessment, **call the subject** at the telephone number(s) provided on the consent form or other phone number known to be used by the subject. (Subjects may also be reminded of scheduled appointments by mail (see Follow-up visit reminder letter (template available at https://www.nihstrokenet.org/sleep-smart-trial/research-team), phone, email, and/or text message (the latter two if ok with the subject or other contact).)

4. If the site is unable to reach the subject by phone to schedule the appointment, **text and/or email** the subject, if permission provided on the consent. Additionally, send a message through the patient portal.

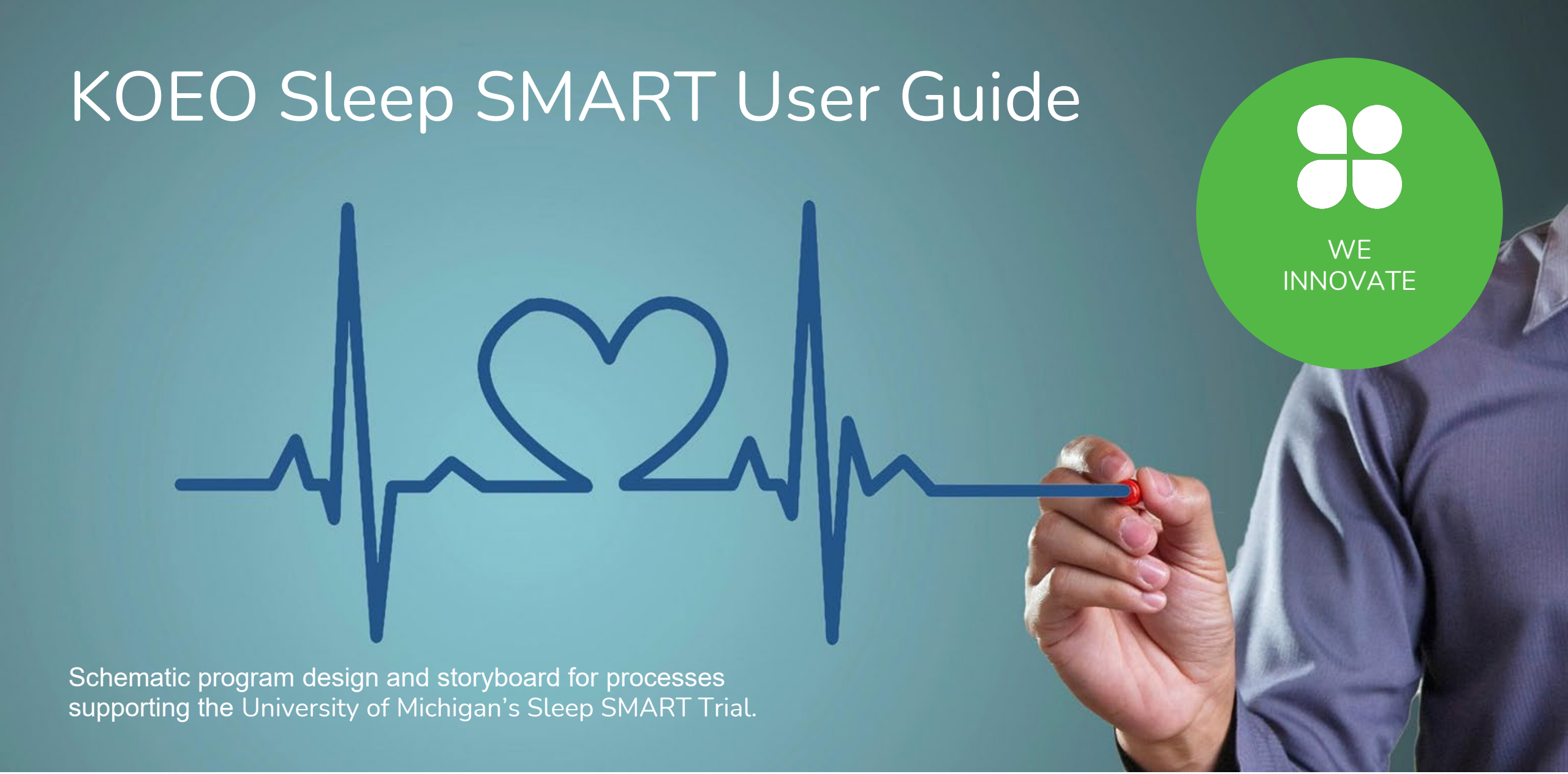
5. If this is unsuccessful, **contact the alternative contacts** listed on the consent form.

6. If the subject is located at a facility (e.g. nursing home), **contact the facility** to see if they can facilitate direct contact with the subject. If the subject is unable to participate in the outcome assessment, **see if any staff member qualifies as a proxy**. Use the medical record release to acquire records to assess for interim events. If a release was not obtained, use the Sleep SMART consent form to try to acquire the records (page 15 includes authorization for release of future records: "You authorize the release of your medical records from the current hospitalization and all hospitalizations during your 6 months of

We love outcomes!

- Outcomes are for all randomized subjects
- We want outcomes even if intervention participant stopped using CPAP, or if a control participant is using CPAP!
- Some intervention participants may feel guilty about abandoning CPAP
  - We still want their outcomes!

KOEO Sleep SMART User Guide



WE INNOVATE

Schematic program design and storyboard for processes supporting the University of Michigan's Sleep SMART Trial.

Sleep

Recover

Perform

ISO 27001

ANAB ACCREDITED

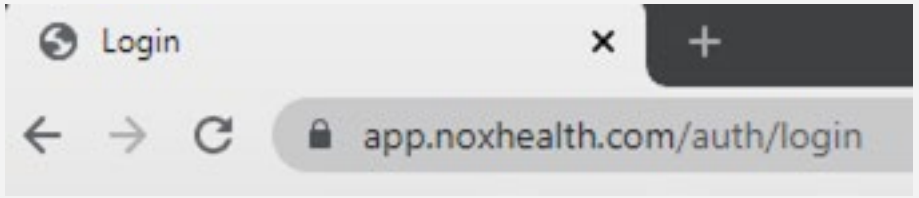
FusionHealth®


KOEO LOGIN & SLEEP
SMART PROCESS
LAUNCH

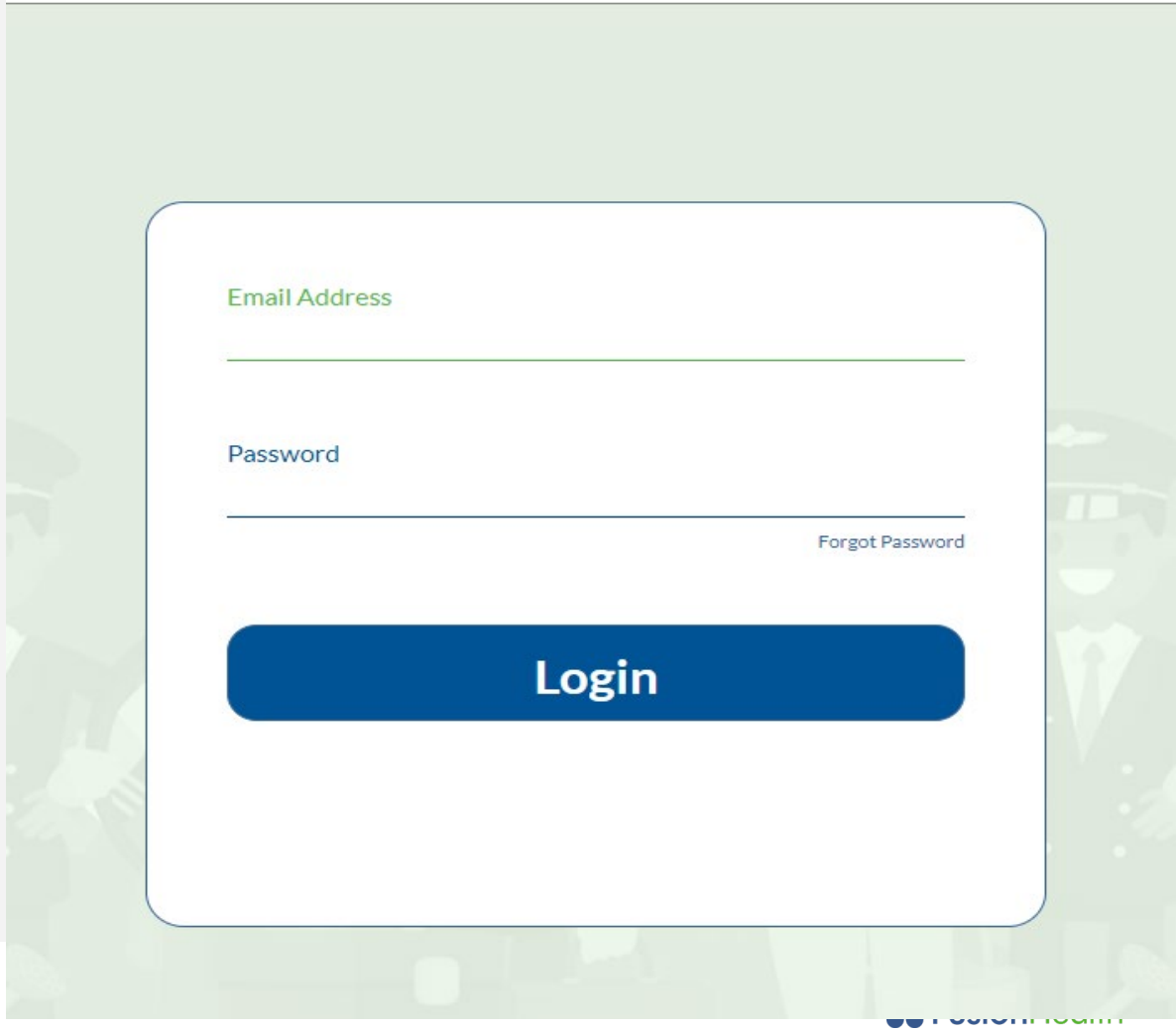
Login to KOEO

Open **Chrome Browser**

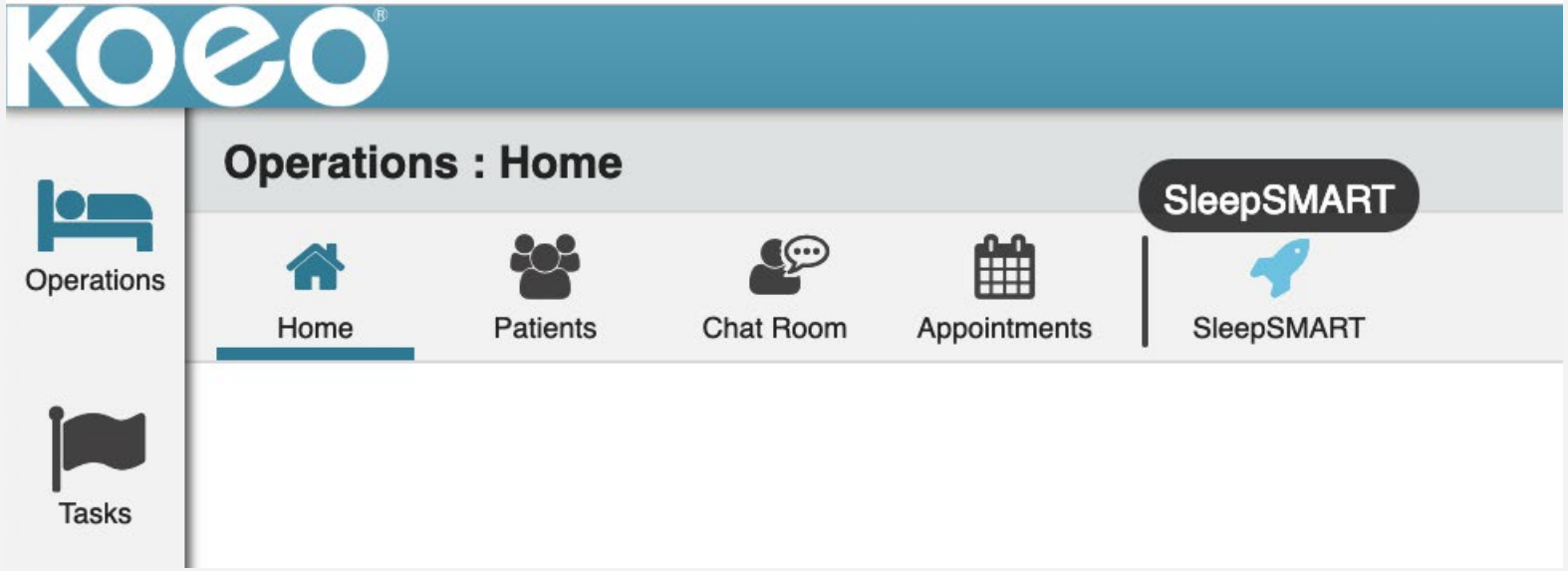
Enter: app.noxhealth.com



Login to KOEO with User email and password

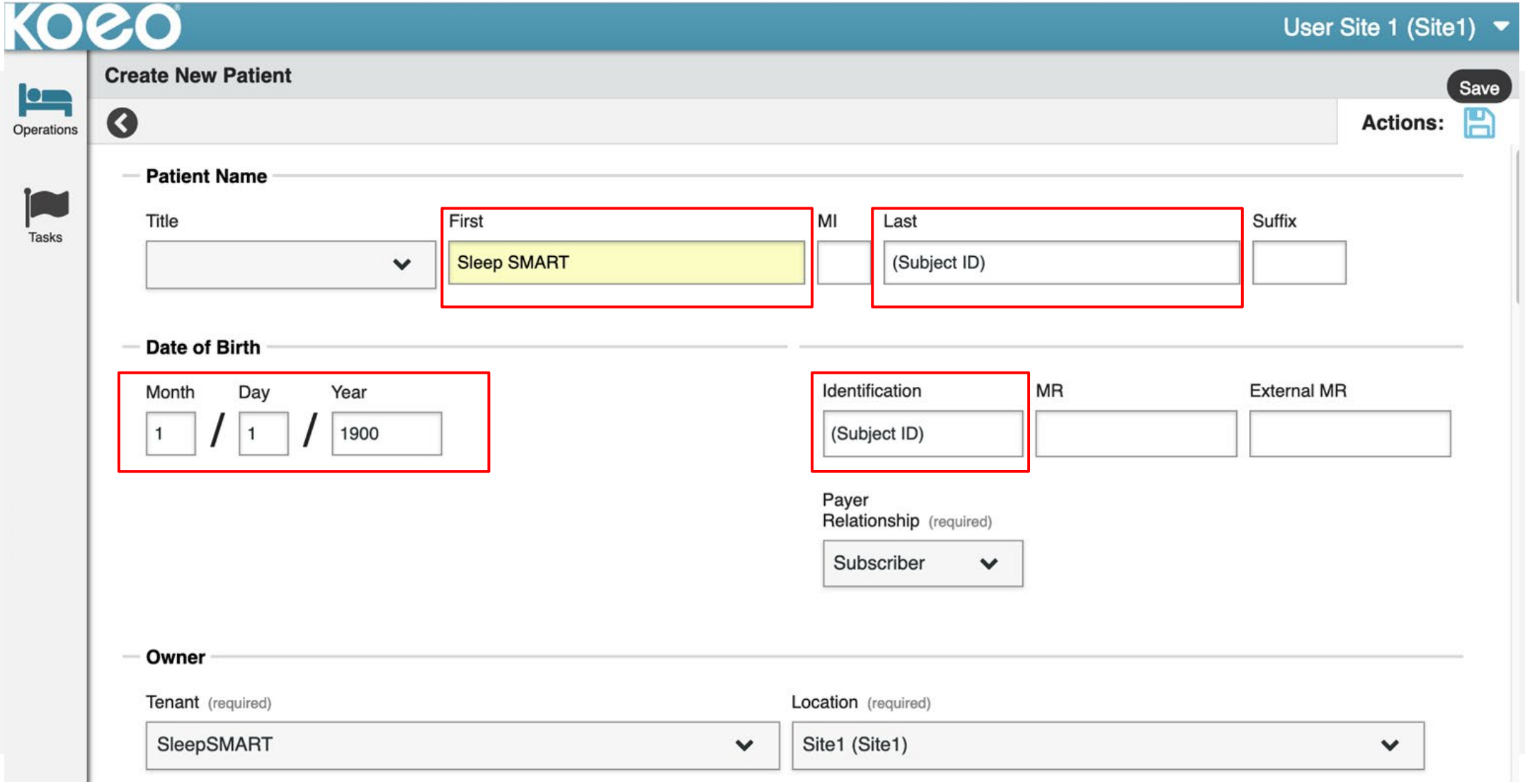


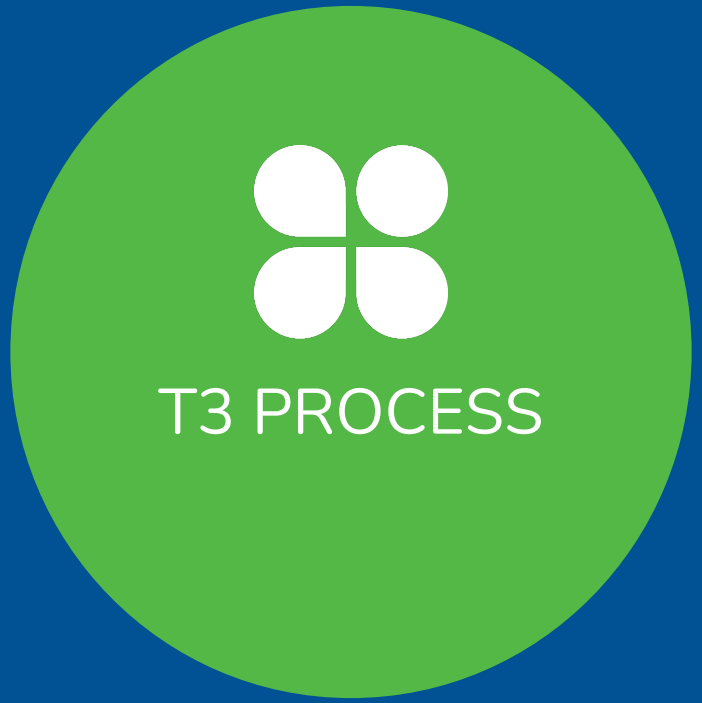
Launch SleepSMART process



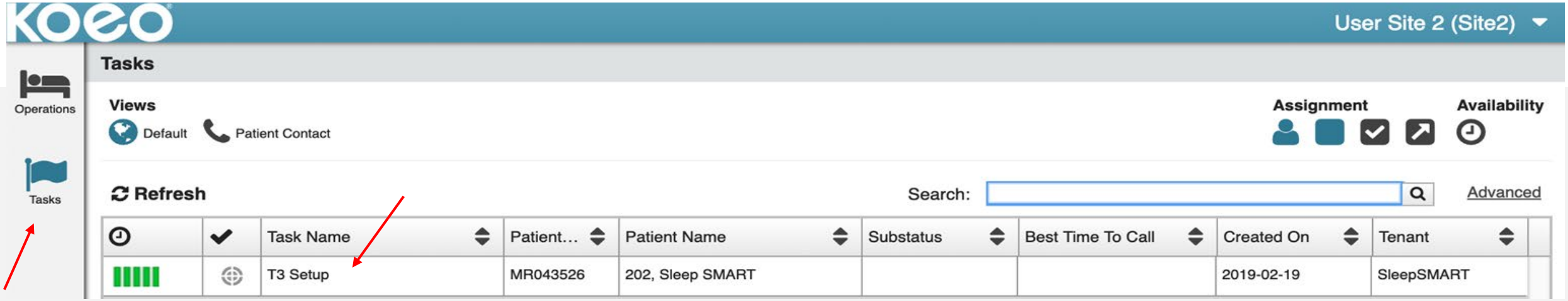
Create New Patient

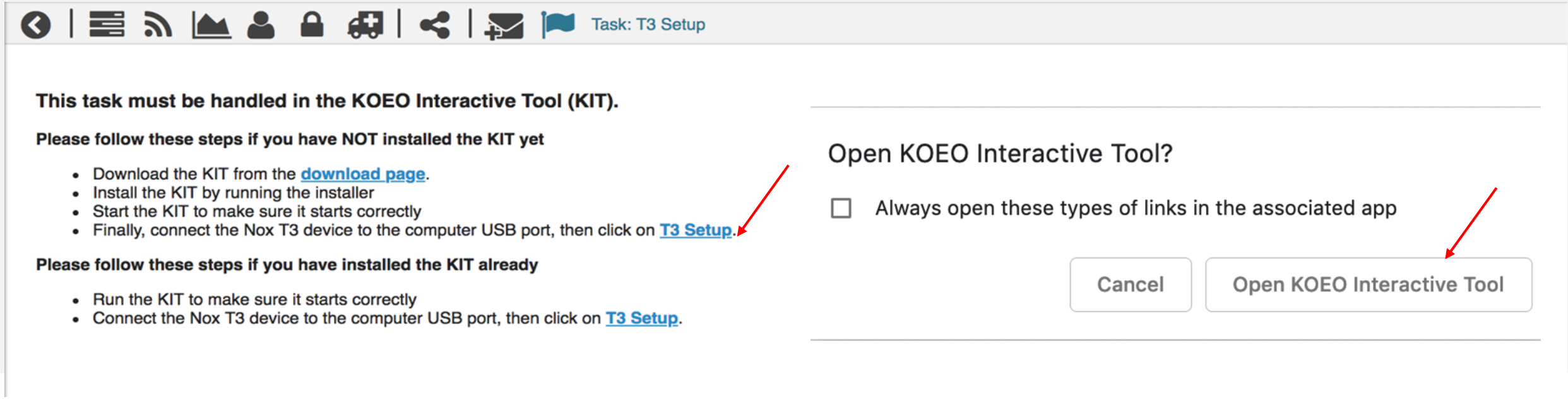
Enter the following fields then click Save on top right.




T3 PROCESS

T3 Setup Task in KOEO



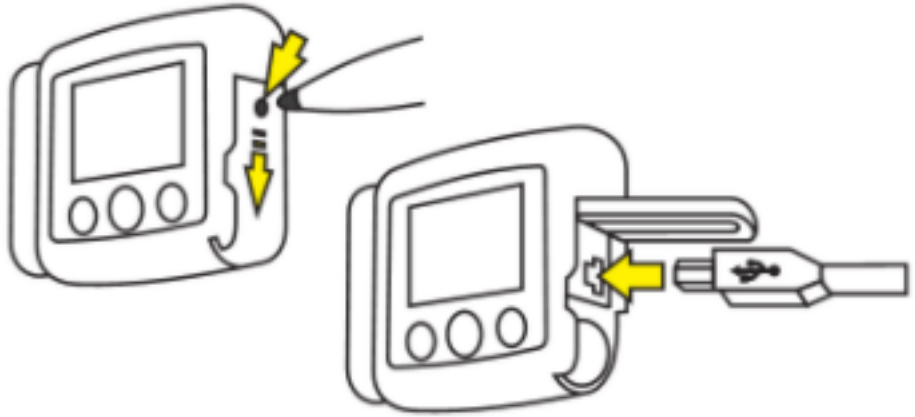


Connecting the T3 to a Computer

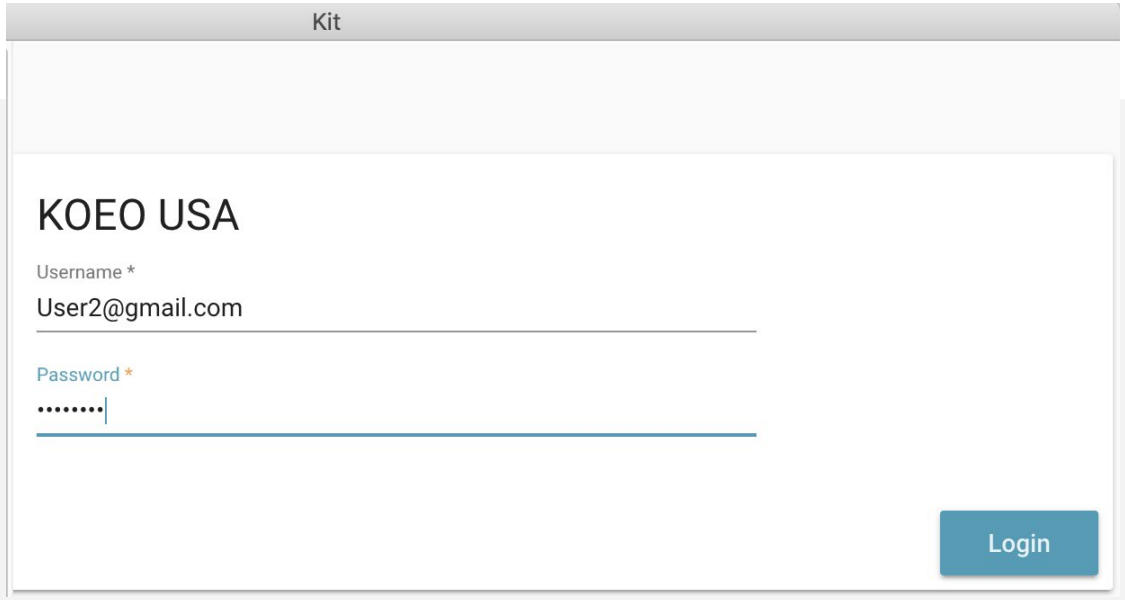
To connect the Nox T3 device to a computer you need to access the USB connector on the device, underneath the battery lid.

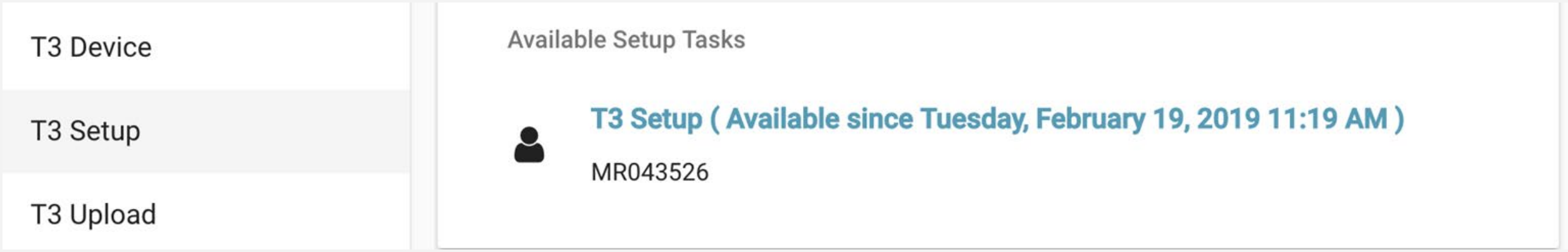
To open the battery lid, press with the battery pen (included) and slide the battery lid down, towards the bottom of the device.

Connect the device to a computer with the provided USB cable.

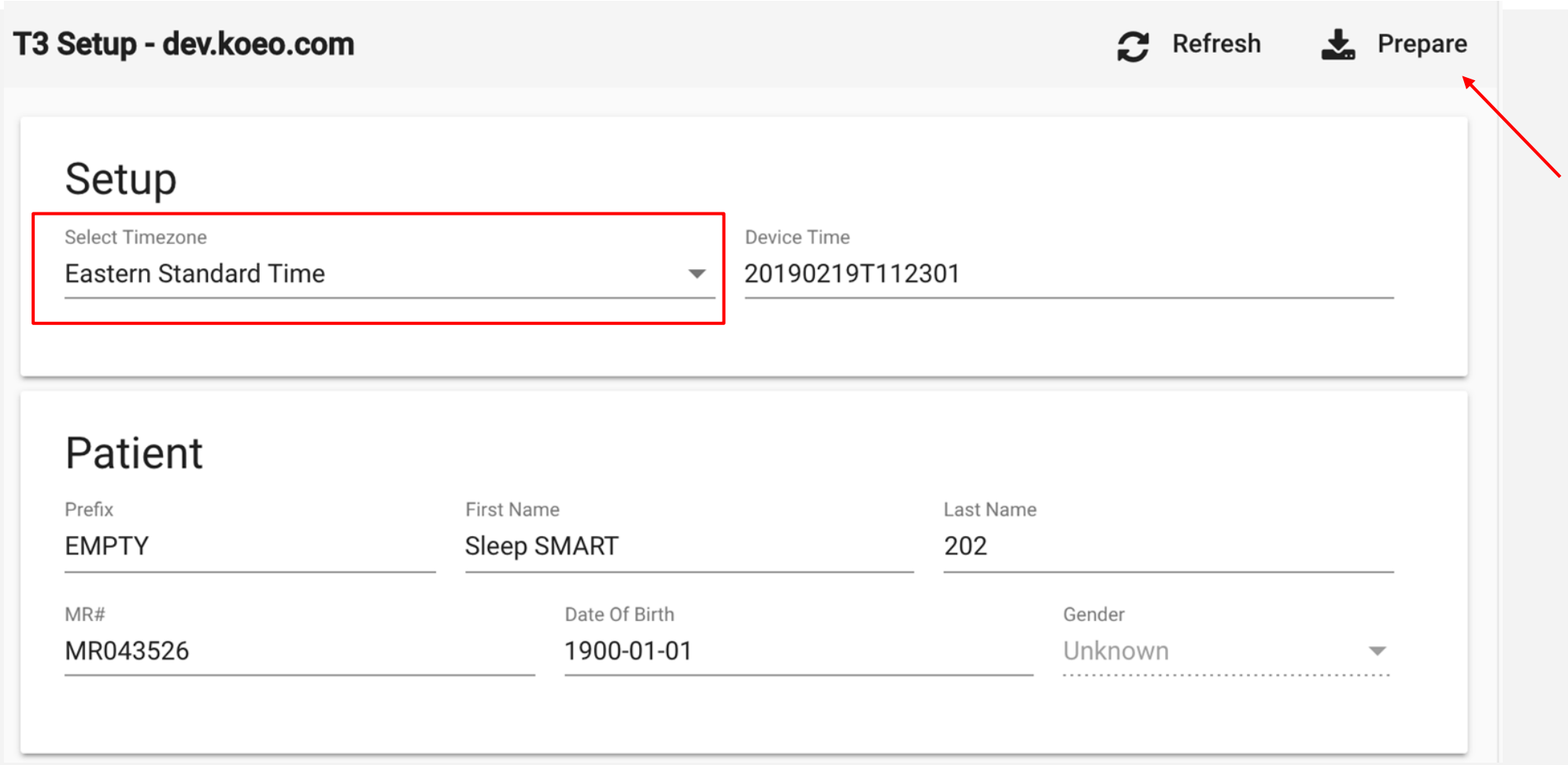


Login and Locate T3 Setup Task in KIT

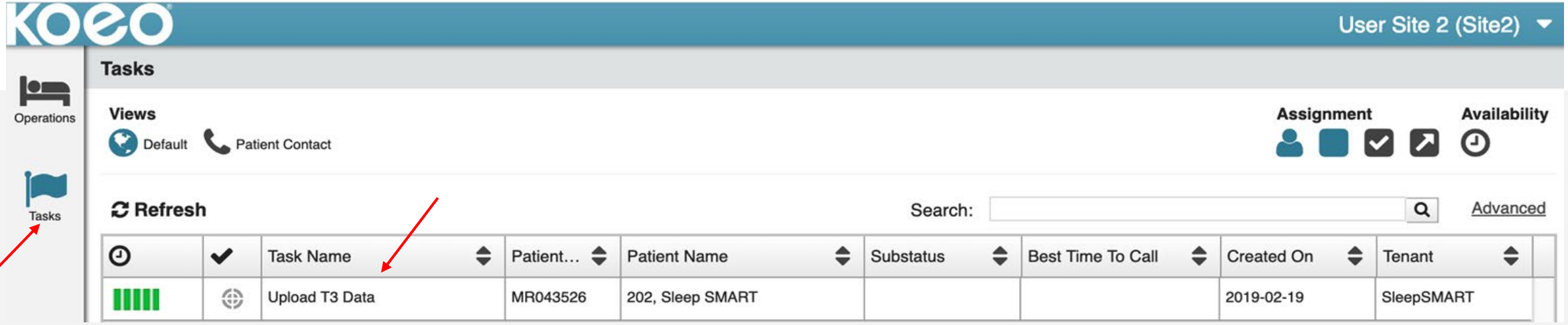


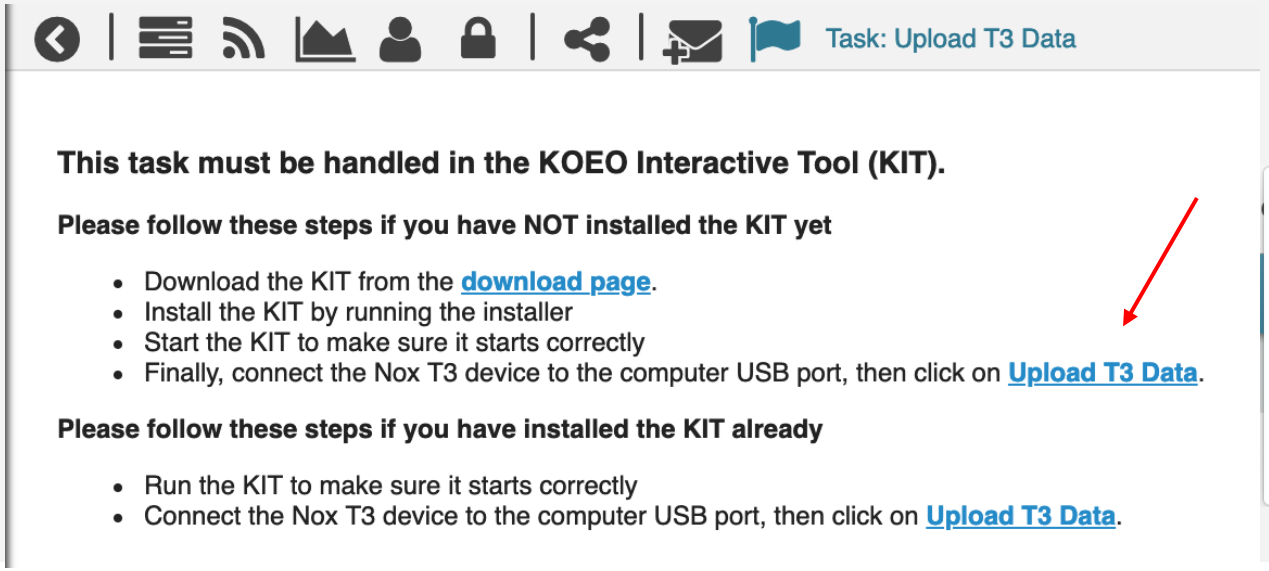


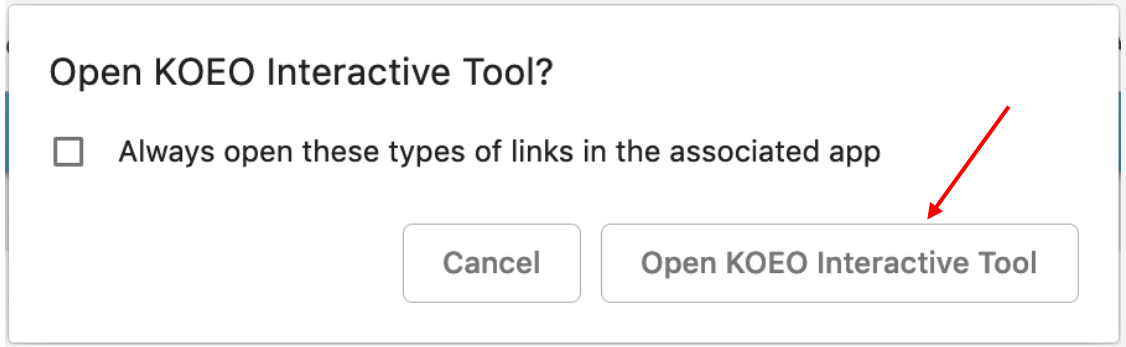
T3 Setup Task in KIT



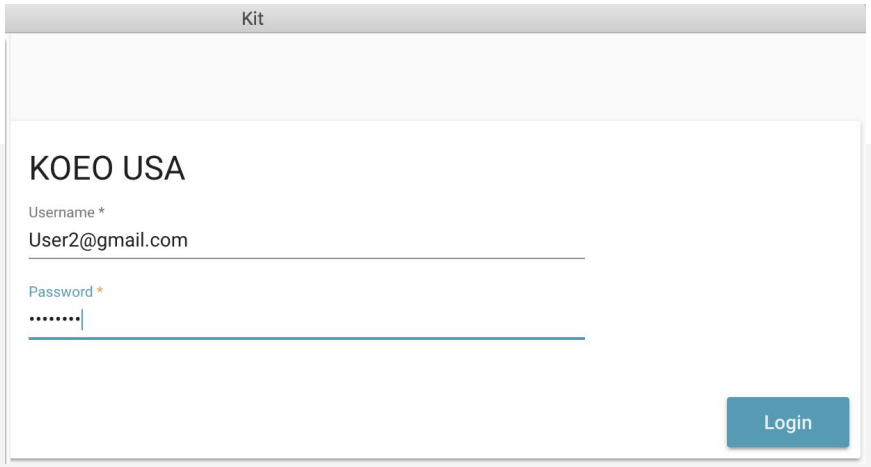
Upload T3 Task in KOEO

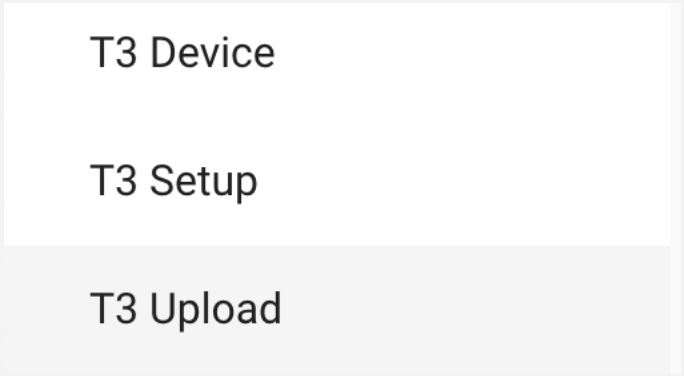




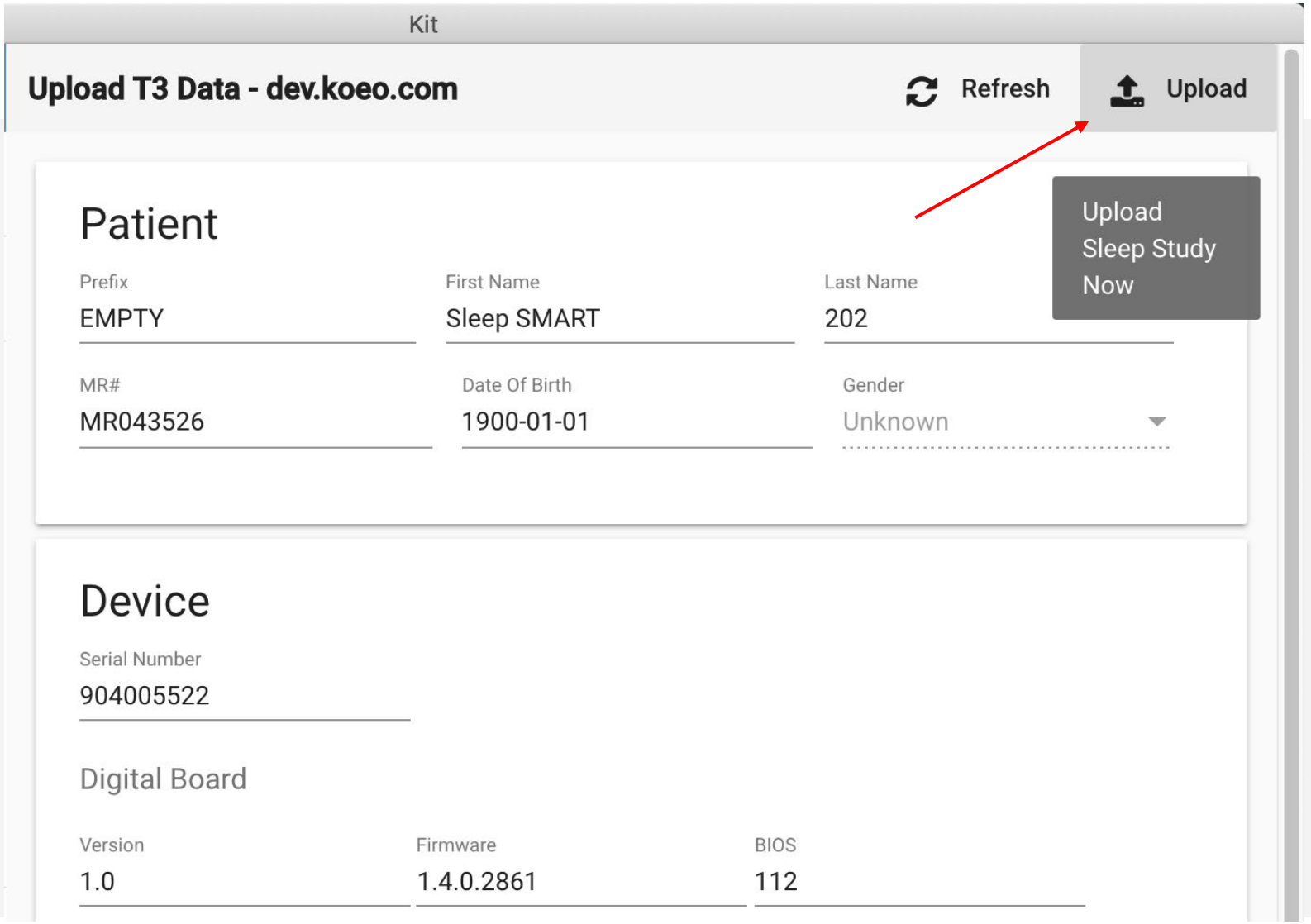


Login and Locate T3 Upload Task in KIT





Will automatically load correct subject data from plugged in T3.



Potential Next Tasks

Task Name	Patie…	Patient Name	Substatus	Best Time To Call	Created On	Tenant
Redo Upload T3 Data	MR043526	202, Sleep SMART			2019-02-19	SleepSMART

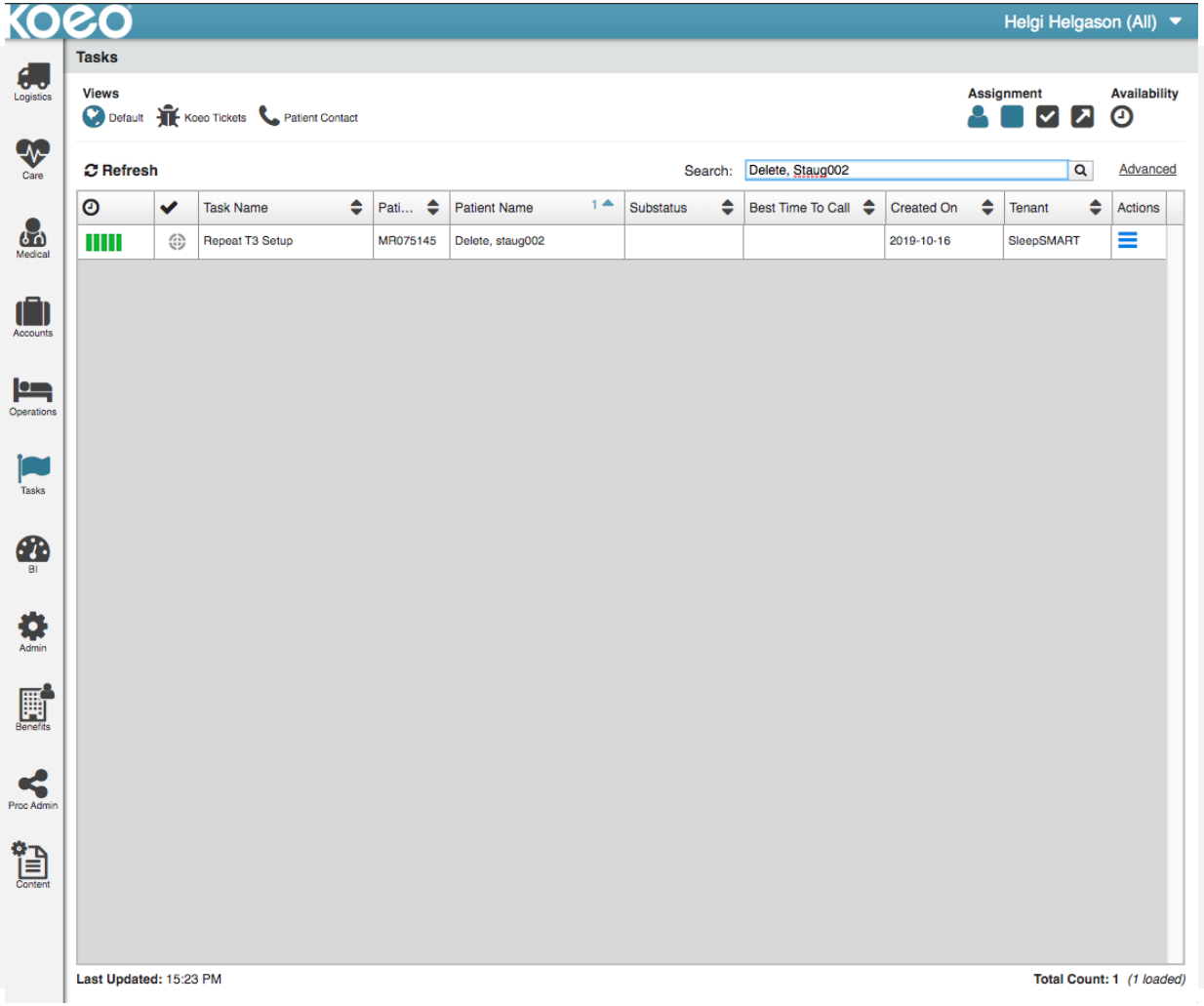
Task Name	Patie…	Patient Name	Substatus	Best Time To Call	Created On	Tenant
Repeat T3 Setup	MR070783	012, Sleep SMART			2019-04-24	SleepSMART

Task Name	Patient…	Patient Name	Substatus	Best Time To Call	Created On	Tenant
T3 Test Inadequate	MR070764	011, Sleep SMART			2019-04-23	SleepSMART

Task Name	Patie…	Patient Name	Substatus	Best Time To Call	Created On	Tenant
Subject Eligible	MR070763	010, Sleep SMART			2019-04-23	SleepSMART

Task Name	Patie…	Patient Name	Substatus	Best Time To Call	Created On	Tenant
Excluded - Print Report	MR070763	010, Sleep SMART			2019-04-23	SleepSMART

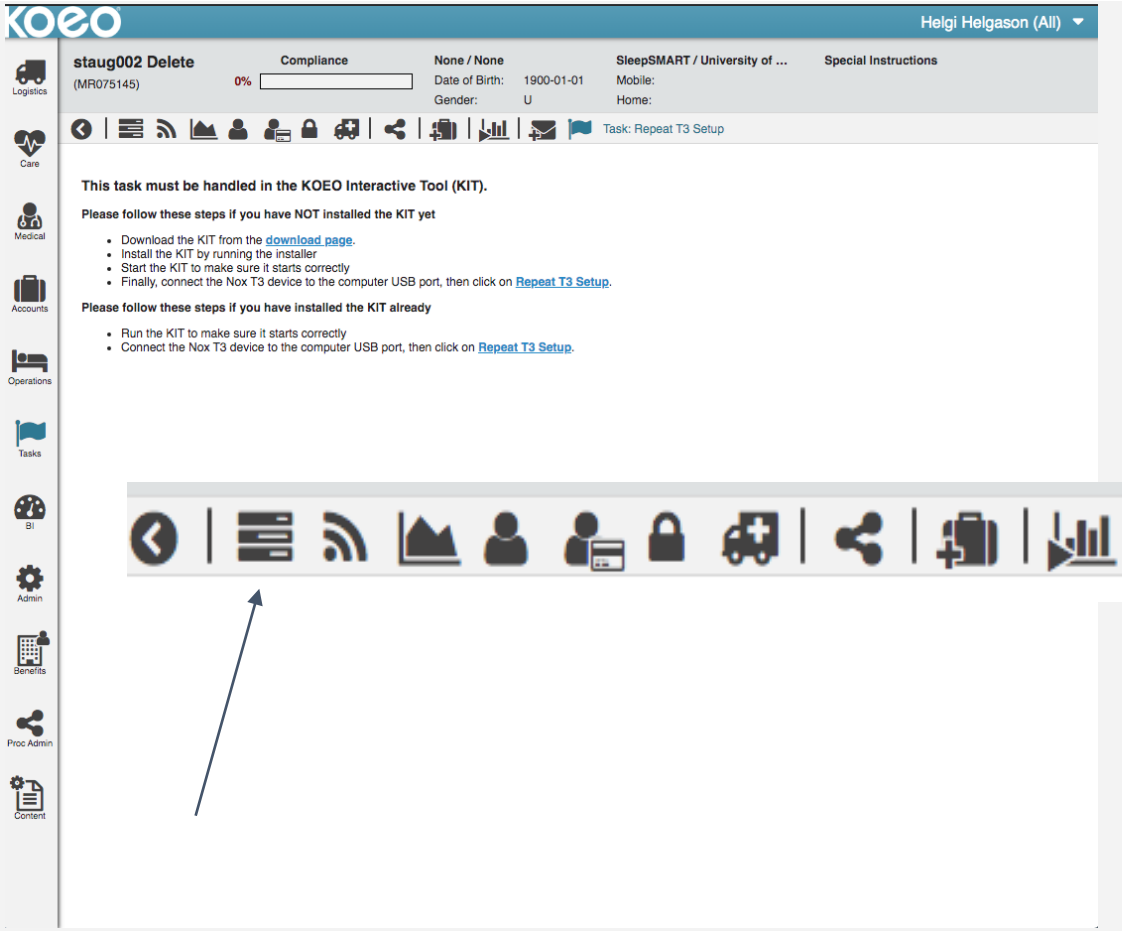
Repeat T3 Setup Task



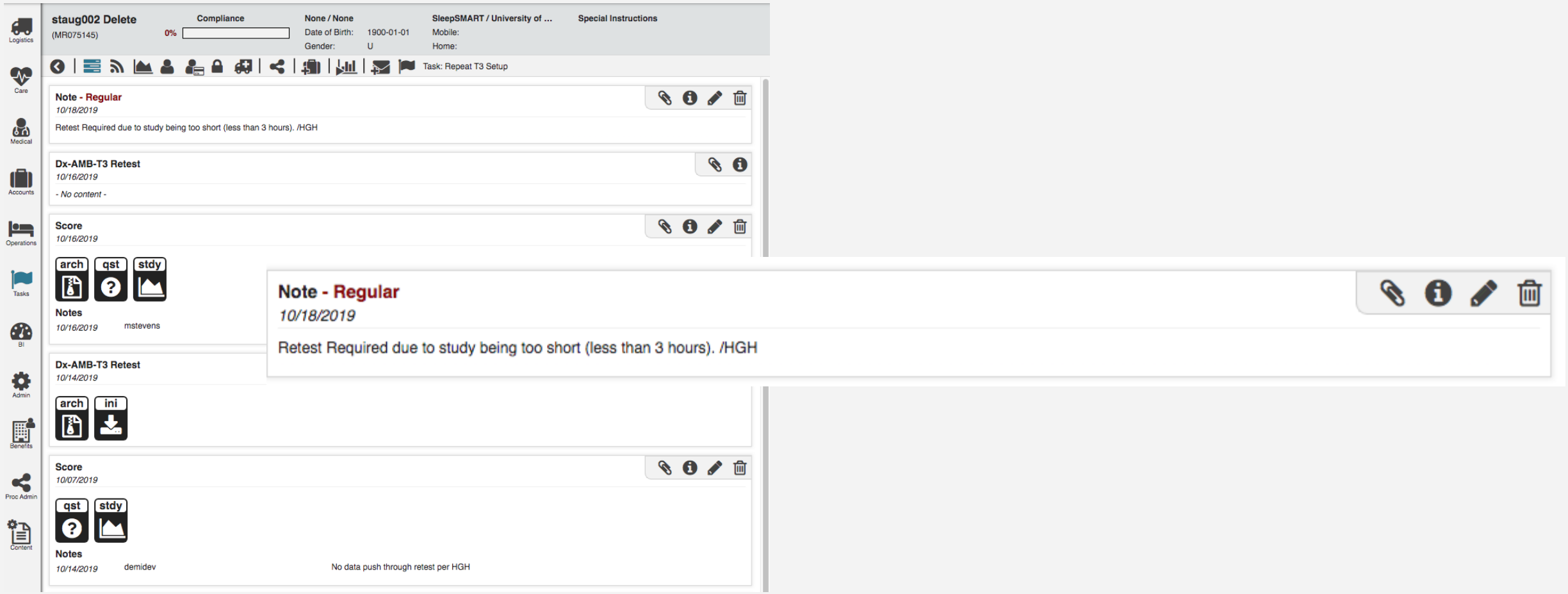
Main reasons for invalidating tests:

- Less than 3 hours of data
- No belts
- No data on device - did not start

From the task, go to Subject's Timeline



The Timeline in KOEO



Invalid Study Questions

Questionnaire Definition Version: 3

Invalid Study Questions

Created On	Started On	Completed On
September 15, 2020 at 3:22:41 PM GMT-4	September 15, 2020 at 3:22:41 PM GMT-4	September 15, 2020 at 3:22:50 PM GMT-4

Should there be a retest?

Yes

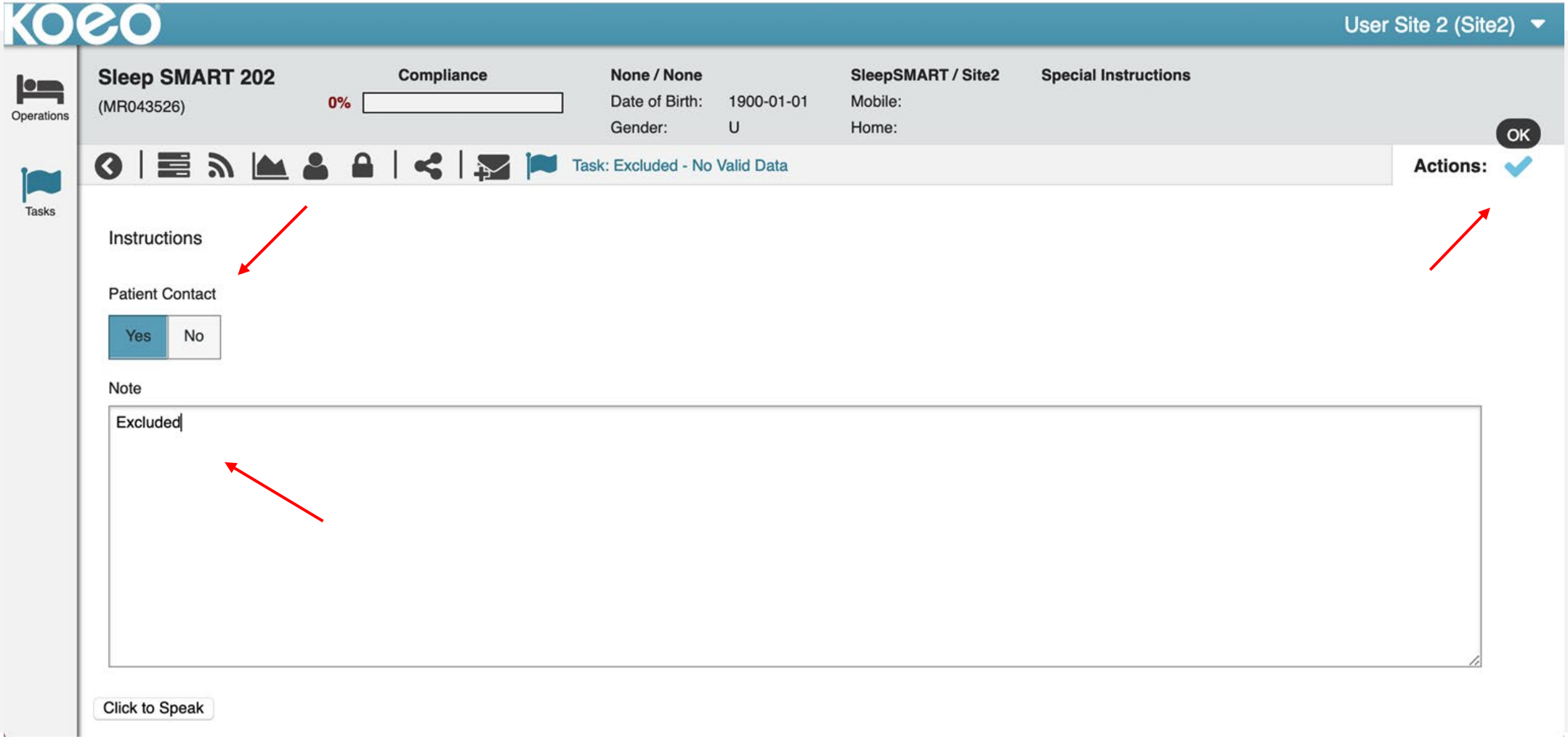
Why was the study invalid?

Missing belts

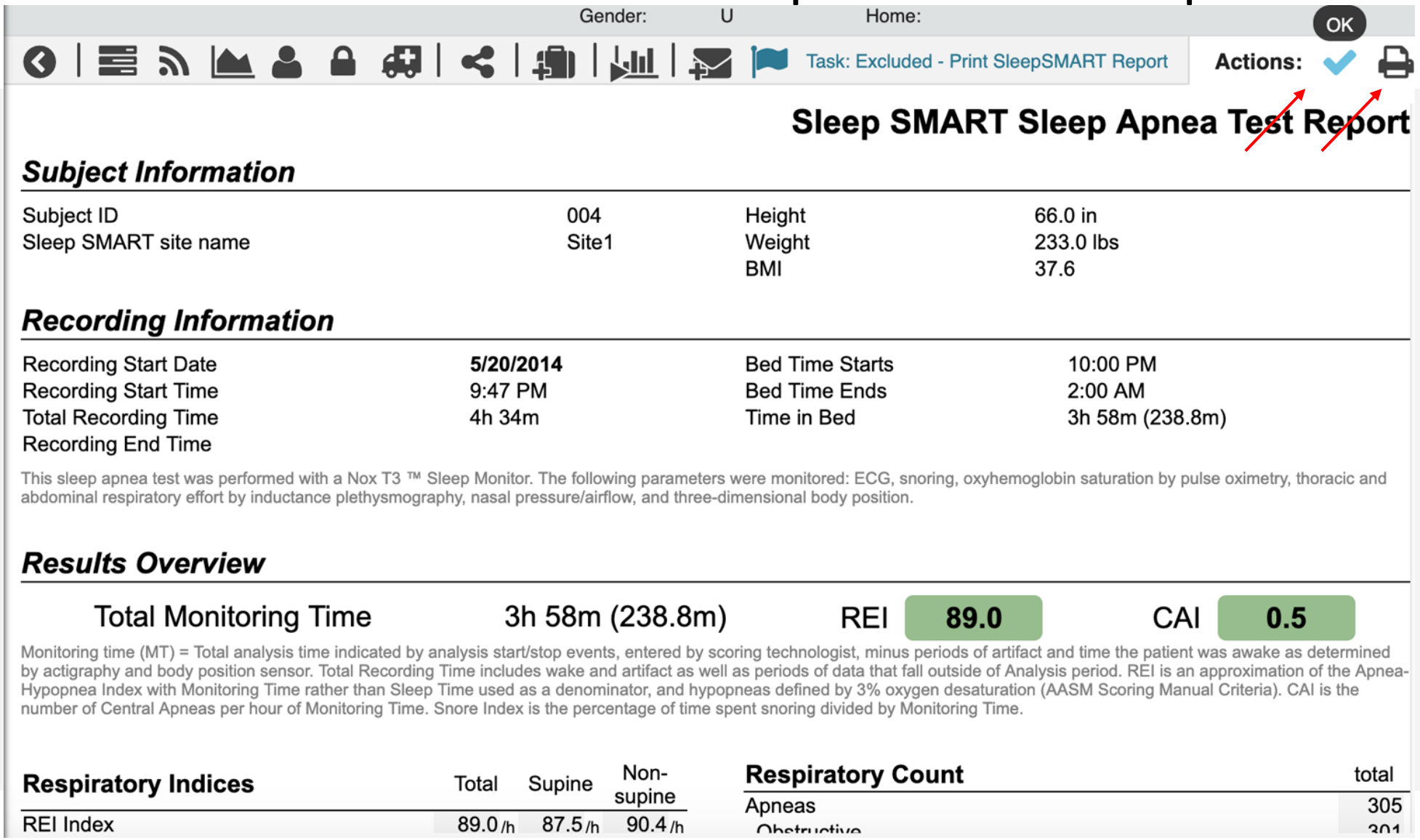
Additional description

flow, abdomen or thorax signals were all missing for the entire study

Excluded - No Valid Data



Excluded - Print SleepSMART Report



Sleep SMART Sleep Apnea Test Report

Subject Information

Subject ID	004	Height	66.0 in
Sleep SMART site name	Site1	Weight	233.0 lbs
		BMI	37.6

Recording Information

Recording Start Date	**5/20/2014**	Bed Time Starts	10:00 PM
Recording Start Time	9:47 PM	Bed Time Ends	2:00 AM
Total Recording Time	4h 34m	Time in Bed	3h 58m (238.8m)
Recording End Time			

This sleep apnea test was performed with a Nox T3 ™ Sleep Monitor. The following parameters were monitored: ECG, snoring, oxyhemoglobin saturation by pulse oximetry, thoracic and abdominal respiratory effort by inductance plethysmography, nasal pressure/airflow, and three-dimensional body position.

Results Overview

Total Monitoring Time	3h 58m (238.8m)	REI	**89.0**	CAI	**0.5**

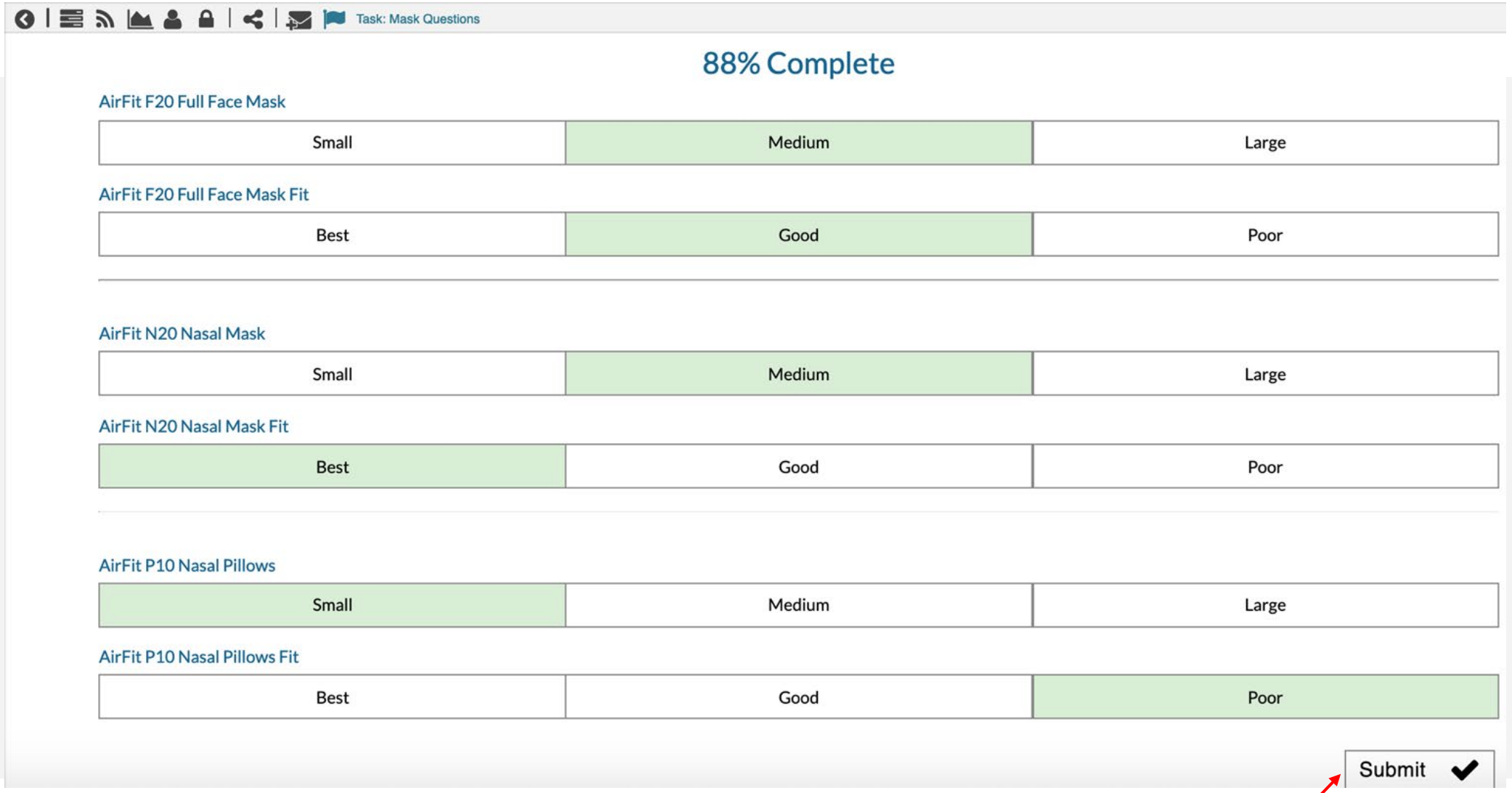
Monitoring time (MT) = Total analysis time indicated by analysis start/stop events, entered by scoring technologist, minus periods of artifact and time the patient was awake as determined by actigraphy and body position sensor. Total Recording Time includes wake and artifact as well as periods of data that fall outside of Analysis period. REI is an approximation of the Apnea-Hypopnea Index with Monitoring Time rather than Sleep Time used as a denominator, and hypopneas defined by 3% oxygen desaturation (AASM Scoring Manual Criteria). CAI is the number of Central Apneas per hour of Monitoring Time. Snore Index is the percentage of time spent snoring divided by Monitoring Time.

Respiratory Indices	Total	Supine	Non-supine
REI Index	89.0 /h	87.5 /h	90.4 /h

Respiratory Count	total
Apneas	305
Obstructive	301

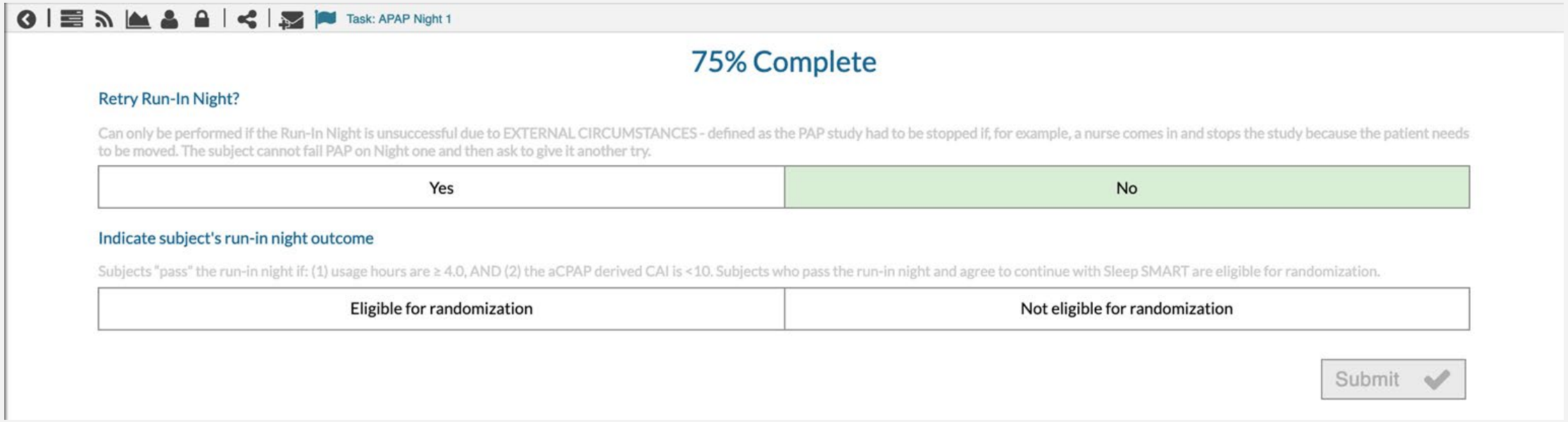

RUN-IN NIGHT
PROCESS

Mask Questions Task

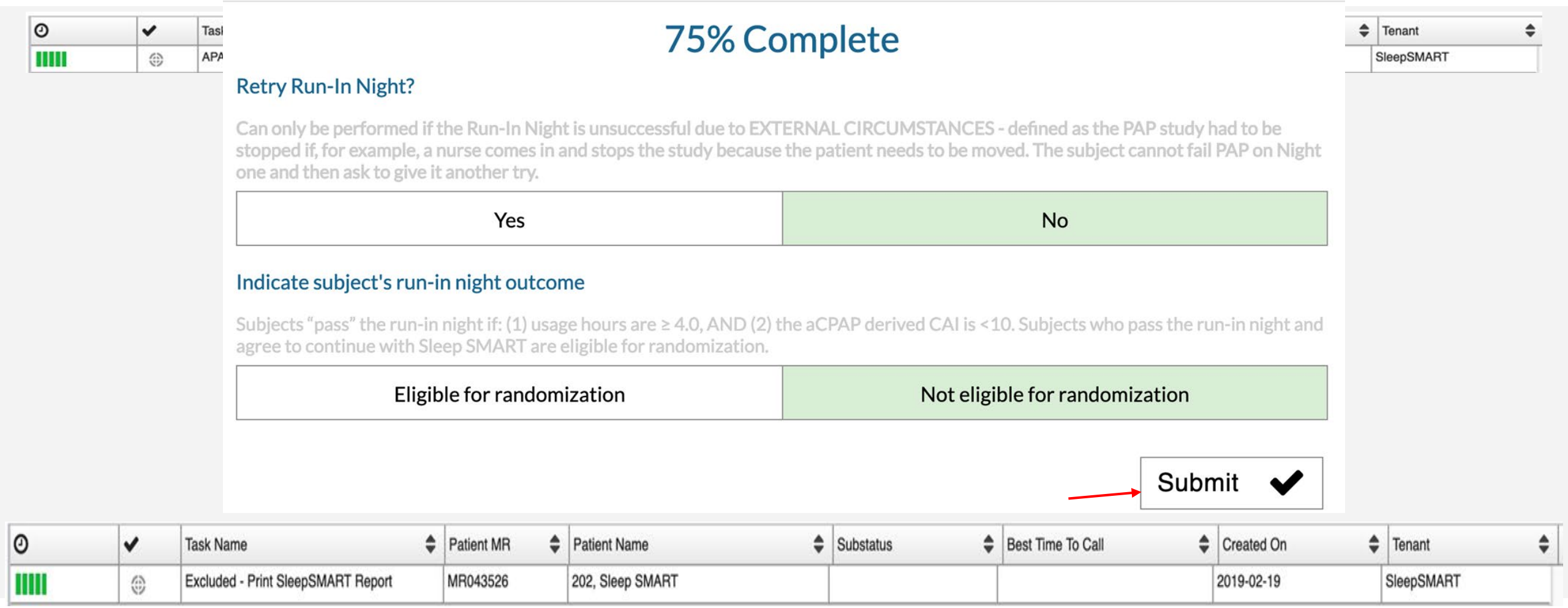


APAP Task

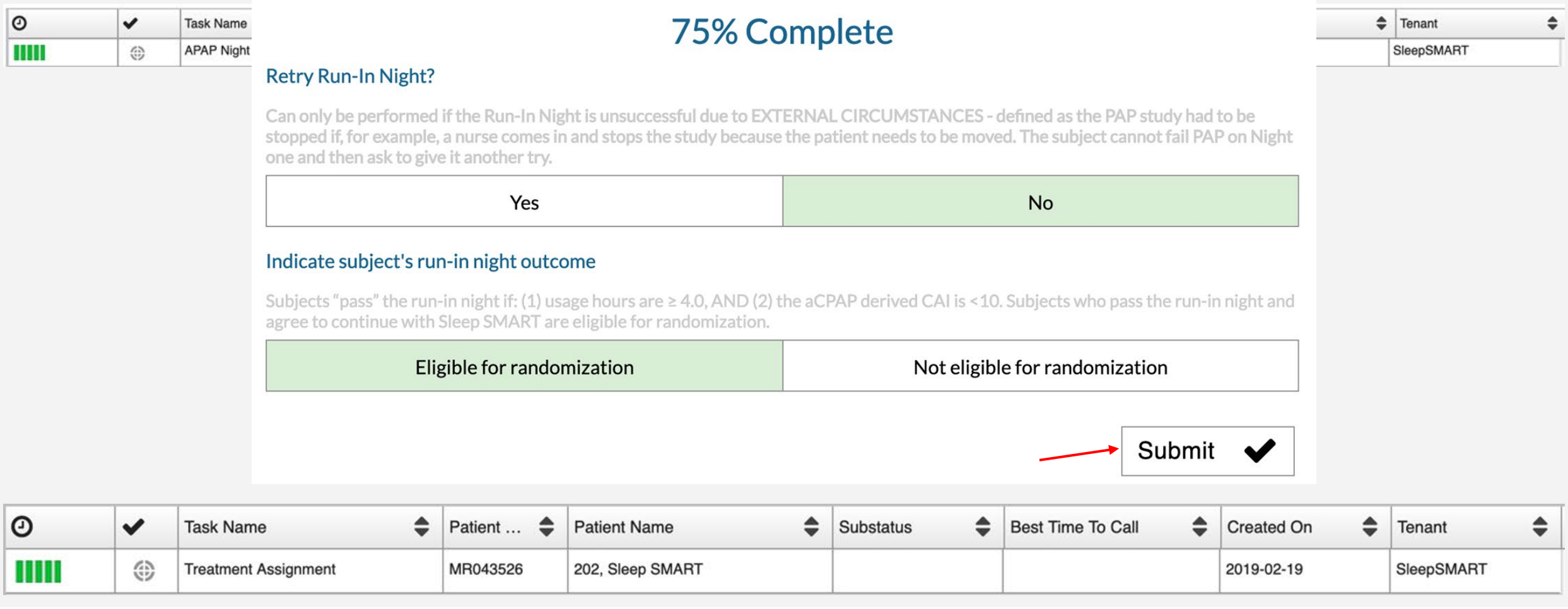
		Task Name	Patient MR	Patient Name	Substatus	Best Time To Call	Created On	Tenant
		APAP Night 1	MR043526	202, Sleep SMART			2019-02-19	SleepSMART



APAP Outcome Not Eligible

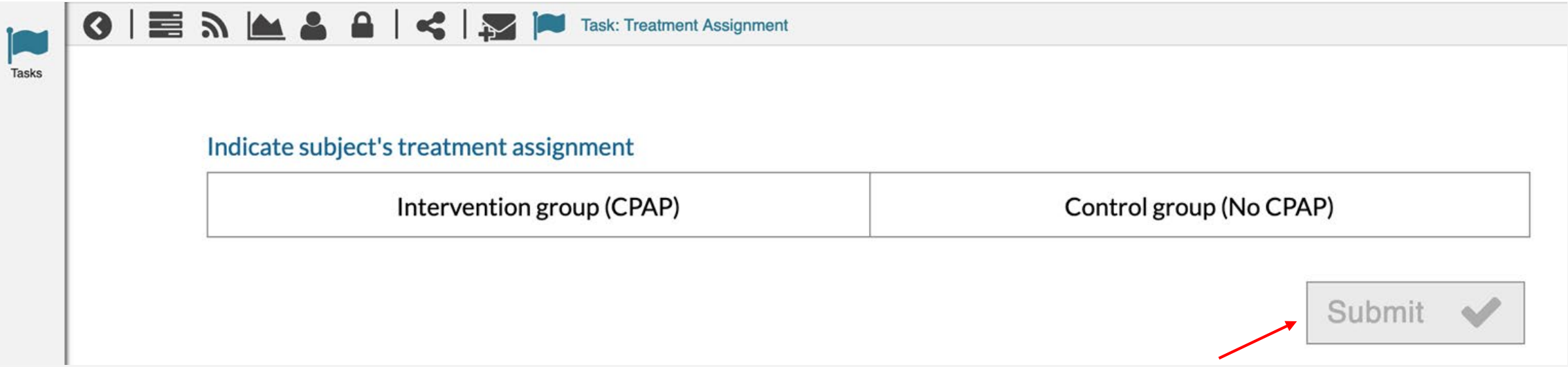


APAP Outcome Eligible



		Task Name	Patient …	Patient Name	Substatus	Best Time To Call	Created On	Tenant
		Treatment Assignment	MR043526	202, Sleep SMART			2019-02-19	SleepSMART

Treatment Assignment Task



If No CPAP - select Control Group (No CPAP) and click Submit. No more tasks and the process is complete.
If CPAP - select Intervention group (CPAP) and click Submit. Next Task will be Enter Patient Info.

Enter Patient Info Task

Update Patient Demographics

		Task Name	Patient …	Patient Name	Substatus	Best Time To Call	Created On	Tenant
		Enter Patient Info	MR043526	202, Sleep SMART			2019-02-19	SleepSMART

Task: Enter Patient Info

Actions:

Patient Name

Title | First: John | MI | Last: Doe | Suffix

Date of Birth

Month: 01 / Day: 01 / Year: 1945

Identification: 202 | MR: MR043526 | External MR

Payer Relationship (required): Subscriber

Owner

Tenant: SleepSMART | Location: Site2

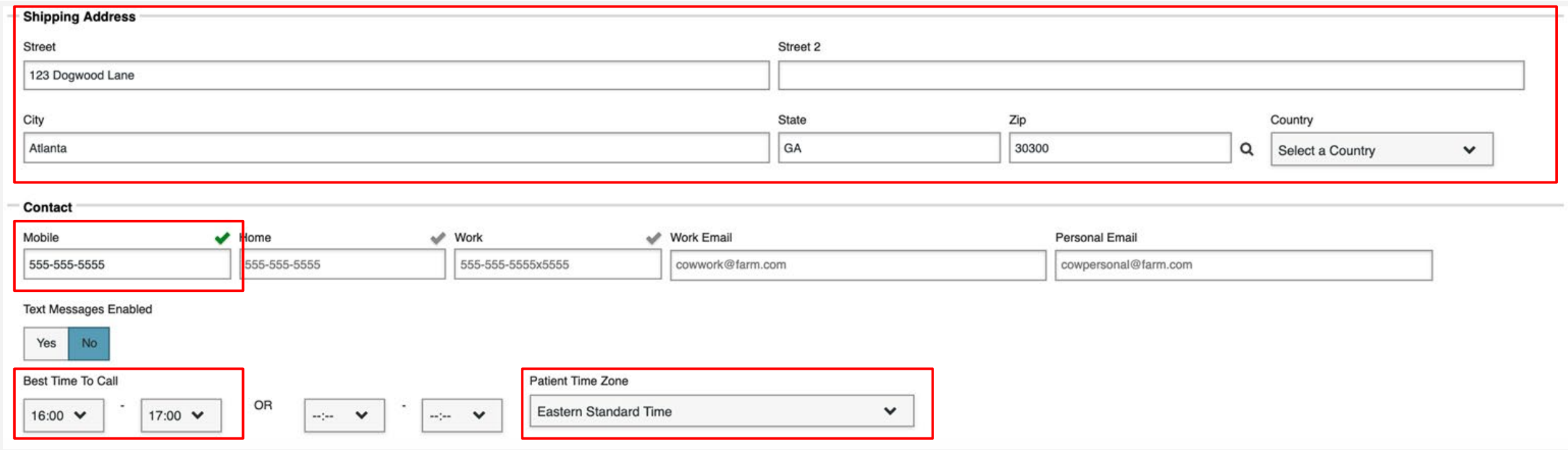
Exception Group: Default Exception Rule

Address

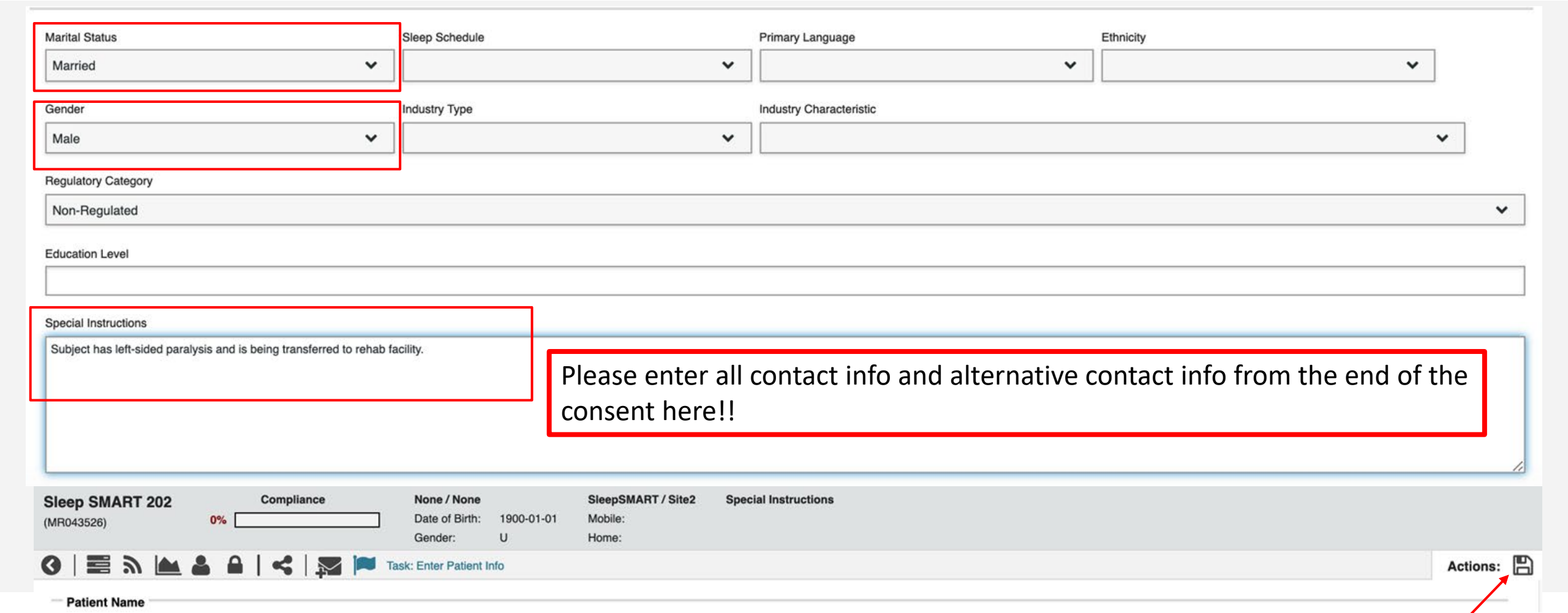
Street: 123 Dogwood Lane | Street 2

City: Atlanta | State: GA | Zip: 30300 | Country: Select a Country

Enter Patient Info Task Continued

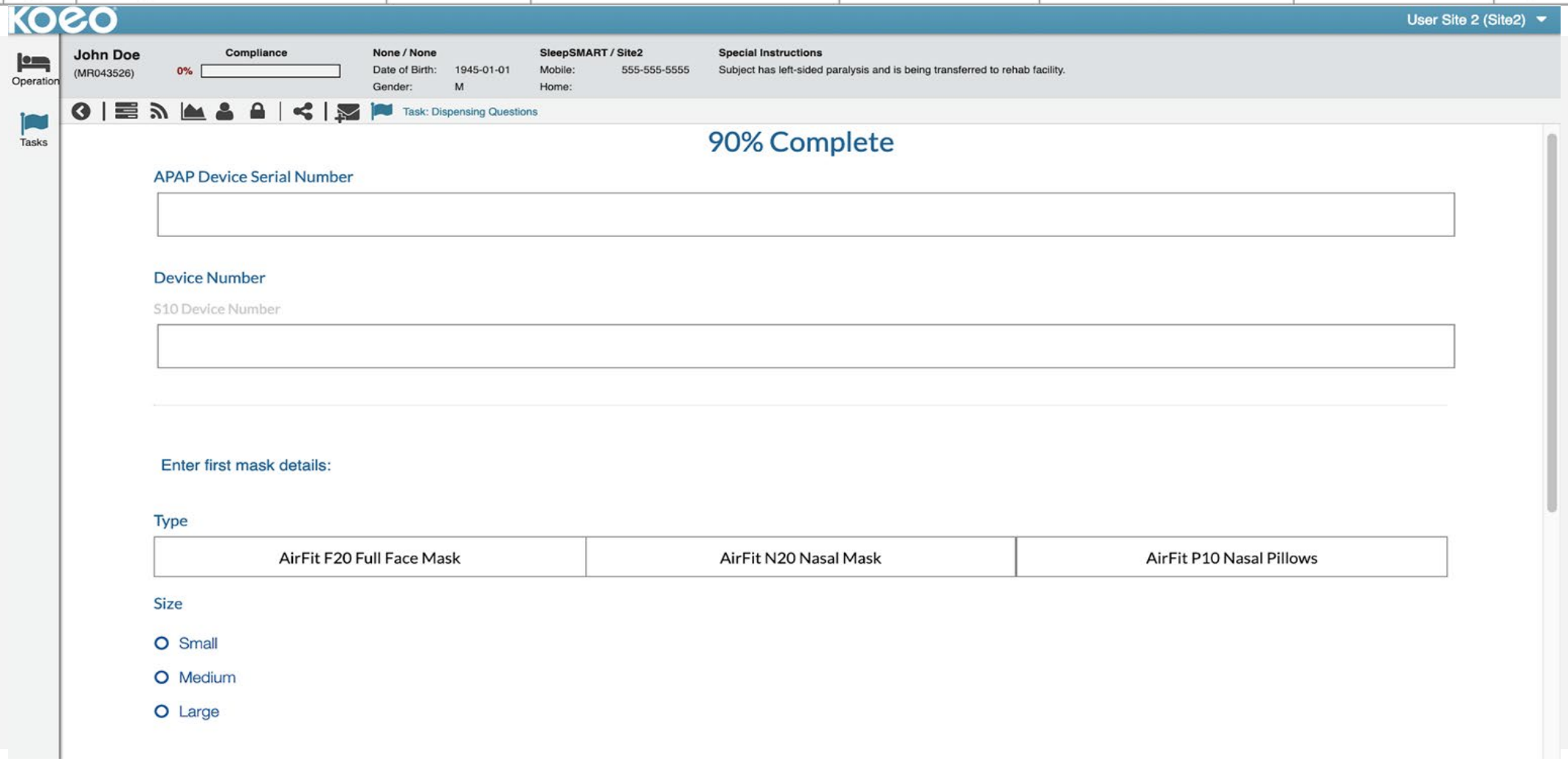


Enter Patient Info Task Continued

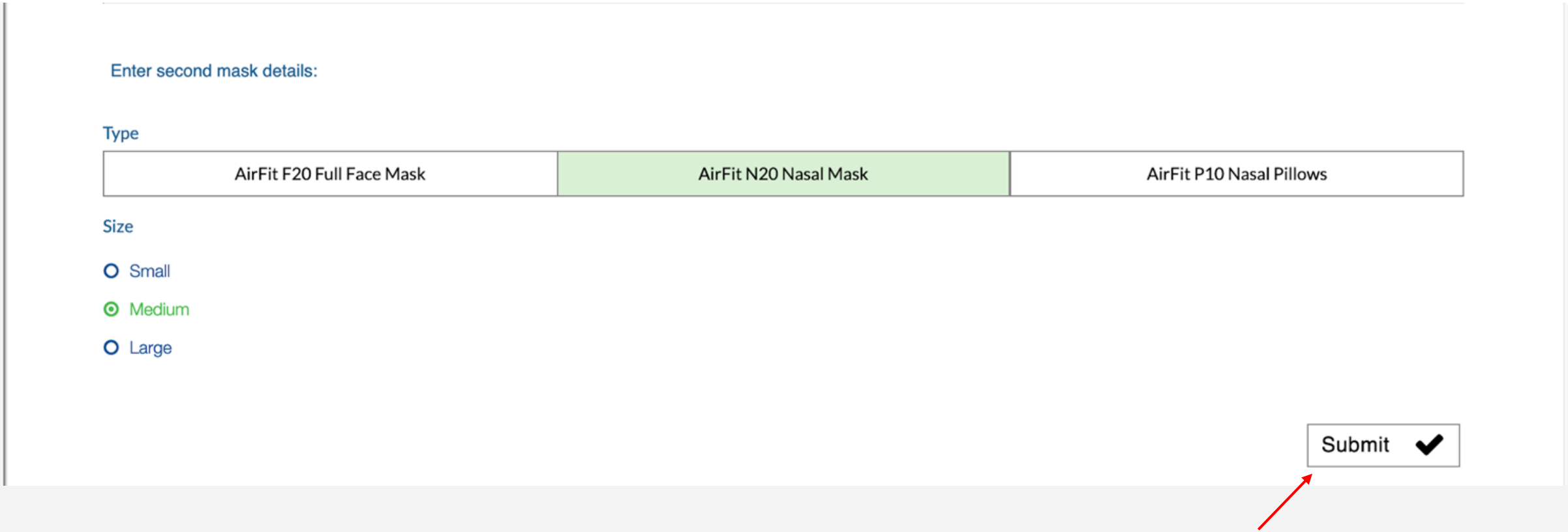


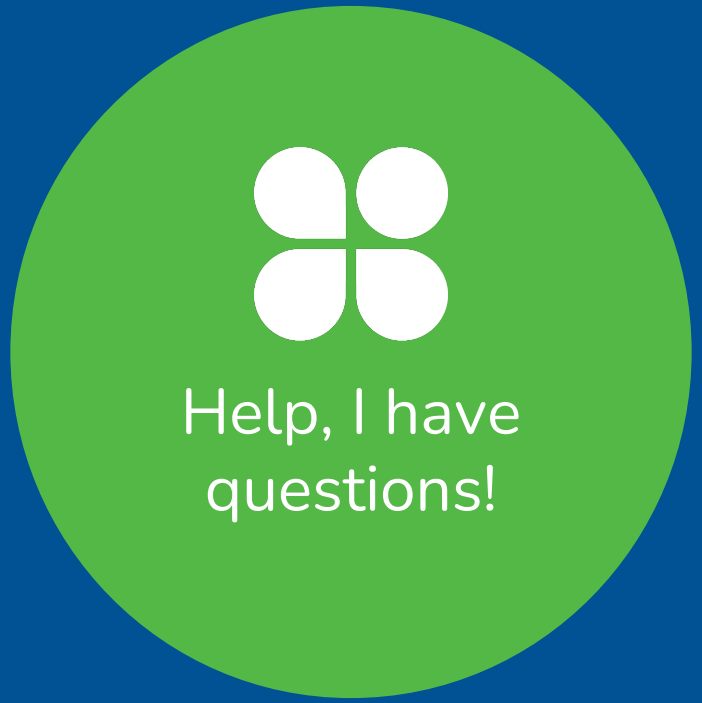
Dispensing Questions Task

		Task Name	Patient MR	Patient Name	Substatus	Best Time To Call	Created On	Tenant
		Dispensing Questions	MR043526	Doe, John		16:00 - 17:00 (EST)	2019-02-19	SleepSMART



Dispensing Questions Task Continued




Help, I have
questions!

New Resource!

UMich will send out a new resource to you after this meeting

This is a “what to do when what you thought worked didn’t work” kind of guide!

Email: SleepSmart TechSupport@ Noxhealth.com

If after hours, please use email rather than phone. We will respond back to email as quickly as we can, typically within a couple hours. Occasionally, we'll need up to 24 hours if the issue relates to a bigger technical problem.

Phone: 404-480-5149

Contact

- KOEO/T3/CPAP: sleepsmarttechsupport@noxhealth.com
- Question about eligibility criterion: Email: sleepsmart@umich.edu
- WebDCU questions:
  - Jocelyn Anderson (anderjoc@musc.edu, 843-876-1167), or
  - Faria Khattak (khattak@musc.edu, 984-221-0266)
  - Katie Trosclair (trosclak@musc.edu) If you have WebDCU-related DOA/regulatory database questions, Informed Consent, Remote or Site Monitoring questions
- Unsure?: kcgossel@med.umich.edu or sicklejb@ucmail.uc.edu