# Medidata User Testing Results + Insights





Methodology

**Test Results** 

PD + Non PD Site Issue - Issue Management Non-PD Study Issue - Issue Management Monitoring Visit - Site Management

**Study Management** 

**Recommendations** 

### Methodology

| How we conducted the tests      | Test areas  |                                       |
|---------------------------------|---|---------------------------------------|
| Task-based Usability Tests      | PD Site Issue - Issue Management  | Monitoring Visit - Site Management    |
| UserZoom (Advanced UX Research) | Non-PD Site Issue - Issue Management  | Study Management                      |
| Screen Recording                | Non-PD Study Issue - Issue Management   |                                       |
| Quantitative Metrics            |   |                                       |
| Difficulty of Task              | How many testers per test   | Roles of testers                      |
| Time on Task                    | 3-5 per test x 5 tests  | CTM CTA                               |
| Successful/Unsuccessful         |   | LTM SM                                |
| Number of Clicks                | Why these tests   |                                       |
| Qx Score Questionnaire          | They provide the greatest range of usability of the application for all 3 roles (CTM_ITM) | data to assess the current experience |

 $of the application for all 5 foles (C five, <math>\Box five, S vert)$ .

# PD + Non-PD Site Issue

**Issue Management** 

### Task Summary

#### Testers: CTM, LTM, SM





Task 1 - Create a PD Site Issue

#### Scenario

Subject XXXX1 took a prohibited herbal supplement, Lyon's Mane 100 mg, on Day 3 of the screening period.

#### **Create a PD site issue**

1. Open study record 42847922MDD2002

- 2. Click on "USA" as country.
- 3. Click on "Site Number 1001"

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ifficult or easy was it to complete this task?

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| cre<br>op <sup>r</sup><br><b>Jevi</b> | eate not could find Select one of the most popular used in the sar   | words to see other words<br>me phrase       |
| Answers 4                             | •  | Copy sheet                                  |
| # \$                                  | Answer 🗧   |   |
| 1                                     | Could not find where to add the deviation  | C6091S118_8                                 |
| 2                                     |  |   |
| ۷                                     | Could not find an option to create a deviation. An option was available for Non-PD.  | C6091S118_9                                 |
| 3                                     | Could not find an option to create a deviation. An option was available for Non-PD.<br>Could not complete the task as could not find an option to create a deviation.  | C6091S118_9<br>C6091S118_10                 |
| 2<br>3<br>4                           | Could not find an option to create a deviation. An option was available for Non-PD.<br>Could not complete the task as could not find an option to create a deviation.<br>I was not able to enter in my account. This scenario is simple in my opinion. | C6091S118_9<br>C6091S118_10<br>C6091S118_33 |

| -   |
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| Ans |
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Task 2 - Create Non-PD Site Issue

#### Scenario

Electronic Patient Reported Outcomes (ePRO) tablet is recording erroneous date and time stamp for data. Programming update required through a data transfer to correct. The back-end programming error is impacting hundreds of devices across all countries and majority of sites in the study.

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 Click on "USA" as country.
 Click on "Site Number 1001"

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| <b>vi</b> a<br>s 4 | Answer \$  |  | L° Copy sheet   |
| 4                  | Answer ÷<br>Could not find where to add the deviation  |  | Copy sheet           UZ_ID \$           C6091S118_8   |
| 4                  | Answer ¢<br>Could not find where to add the deviation<br>Could not find an option to create a deviation. An option   | tion was available for Non-PD.                       | Copy sheet     UZ_ID      C6091S118_8     C6091S118_9 |
| 4                  | Answer +<br>Could not find where to add the deviation<br>Could not find an option to create a deviation. | tion was available for Non-PD.                       |   |

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Open study record 42847922MDD2002
 Click on "USA" as country.
 Click on "Site Number 1001"

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|                         |  |





Quality of Experience (Qx) Score

- 1 Strongly Disagree
- 2 Disagree
- 3 Neutral
- 4 Agree
- 5 Strongly Agree

1. Please rate your level agreement to the following statements about this website.





What we heard

| It doesn't really show how to created that in the corner, the button say abandon. | eate a p<br>/s: "Cre |
|---|----------------------|
| I don't see how to create a site level issue.                                     | W                    |
| There aren't any sites showing up when I searched for "1001"                      | 20<br>sh<br>un       |
| I couldn't find the site in my list when I tried to filter.                       | Co<br>fin            |
|   |                      |

Could not find an option to create a deviation. An option was available for Non-PD.

protocol deviation. I don't see an option for reate Non-Study PD Issue", so I have to

Where are my actions? It's only letting me create ne kind of issue.

000 and the study is recruiting. Well, it's recruiting so I hould have been able to use that study to create a PD nless it hasn't enrolled.

ould not complete the task as could not not an option to create a deviation.



### Recommendations

| ∷medidata              |                                |  |              |                       |   |            |                            |                 |               |
|------------------------|--------------------------------|--|--------------|-----------------------|---|------------|----------------------------|-----------------|---------------|
| 🖶 JanssenEDC1-Innovate | studies<br>+ 42847922MDD2002 + | Actions<br>Issue Management <del>-</del> | Production   | nus<br>n. <del></del> | H   | leip - C   | TMS - CRA (                | Site Manager) 👻 | Deborah N     |
| C Overview             | Issues                         | 02                                       |              | æ                     |   |            |                            | Crea            | te Non-PD Stu |
| P Issues               | ,                              |  |              |                       |   |            |                            |                 |               |
| R Actions              |                                |  |              |                       | ▼ Filter  | rs applied | <ul> <li>Search</li> </ul> |                 | 9             |
| 🛱 Settings             | Type                           |  | -            | Status                | Z Al ope  | n issues   | Assignee                   |                 | 🗌 Assign      |
| 21 Teams               | Visibility                     |  |              | Issue Level           |   |            | Subject ID                 |                 |               |
|                        | All                            |  | -            | All                   |   | -          | All                        |                 |               |
|                        | Filter Res                     | set                                      |              |                       |   |            |                            |                 |               |
|                        | Issue ID Issue                 | e Type Category                          | Subcategory  | Severity              | Description   | Subjects   | Status                     | Created - A     | ssignee       |
| < COLLAPSE             | A IM82 Non-                    | Study                                    | Investigator | Minor                 | Investigator<br>Regulatory file<br>incomplete for study |            | Open                       | Jul 19, L       | eanne         |

When landing on the Issues section of Issue Management, the main button label was a source of confusion.

"So I'm going to go back to issue management and see if I can create it, No, there is not an option to create a PD Site Issue. Only an option to create a Non PD Study Issue. I cannot complete this task."





What we heard



Some users expected to be able to create the issue from the "Issues" tab, rather than the "Actions" one

Allow users to take actions and create items within the respective environment

| + CREATE ISSUE | + CREATE ISSUE      |
|----------------|---------------------|
|                | PD Site Issue       |
|                | Non-PD Site Issue   |
|                | PD Study Issue      |
|                | Non- PD Study Issue |
|                | Create Issue #5     |

Medidata: User Testing

| ≡ r | <b>⊞medidata</b>       |  |  |
|-----|------------------------|--|--|
| *   | JanssenEDC1-Innovate - |  |  |
| Q   | Overview               |  |  |
| P   | Issues                 |  |  |
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| ¢   | Settings               |  |  |
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# Non-PD Study Issue

**Issue Management** 

Task Summary

Testers: CTM, CTM, CTM

#### Tasks Summary

Task 1 - Scenario

Task 2 - Create a non-PD study issue

0%

Medidata: User Testing







Task 1 - Create a Non-PD Study Issue

#### Scenario

Electronic Patient Reported Outcomes (ePRO) tablet is recording erroneous date and time stamp for data. Programming update required through a data transfer to correct. The back-end programming error is impacting hundreds of devices across all countries and majority of sites in the study.

#### Create a non-PD study issue

- 1. Select the study record 42847922MDD2002
- 2. Create a non-PD study issue.
- 3. Go through the review process and close it out.

#### 1. How difficult or easy was it to complete this task?





Task 1 - Create a Non-PD Study Issue

#### Scenario

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- 1. Select the study record 42847922MDD2002
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#### 2. Please explain your rating.

5 responses

Chart Data

omize 🗡 🔰 Export 🌱

Most popular words:

### member<sup>added</sup> did first **not** able study issue<sup>can</sup>

Select one of the most popular words to see other words used in the same phrase

| Answers 5 |  | 🗘 Copy sheet |
|-----------|--|--------------|
| # \$      | Answer 🗢   | UZ_ID \$     |
|           | member who had been added.   |              |
| 2         | It would be good, if I can find the member lists who were added to the study. Maybe it's already available on the page, but I was not very sure where I can find it.   | C6091S116_26 |
| 3         | First tiem I did it, it was difficult to find the Issue management section   | C6091S116_44 |
| 4         | When trying to create a non-PD issue I could not complete some fields such as category,<br>subcategory and for this reason the first task could not be completed. The second task<br>either because I did not find the field study record to search for 42847922MDD2002.<br>Either it's not very intuitive or something is wrong with my account because I've been<br>using CTMS for 7 years with no issues, it's kind of frustrating not being able to complete<br>the tasks. Looking forward to your feedback. | C6091S116_59 |
| 5         | I was unable to log in due to I'm unsure the password and username. I am not able to locate an email with the information.   | C6091S116_63 |

Task 1 - Create a Non-PD Study Issue

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- 3. Go through the review process and close it out.

#### 1. Effectiveness



Task 1 - Create a Non-PD Study Issue

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Quality of Experience (Qx) Score

- 1 Strongly Disagree
- 2 Disagree
- 3 Neutral
- 4 Agree
- 5 Strongly Agree

1. Please rate your level agreement to the following statements about this website.

5 responses

The website is easy to use.

It is easy to navigate within

The information on the website is credible.

The information on the website is trustworthy.

I find the website to be

The website has a clean and simple presentation.

> I will likely return to the website in the future.





What we heard

When trying to create a non-PD issue I could not complete some fields such as category, subcategory and for this reason the first task could not be completed. The second task either because I did not find the field study record to search for 42847922MDD2002. Either it's not very intuitive or something is wrong with my account because I've been using CTMS for 7 years with no issues, it's kind of frustrating not being able to complete the tasks.



Medidata: User Testing

| Environments<br>Production - | Help 👻 CTMS - CRA (Site Mar  | nager) 🕶 |
|------------------------------|------------------------------|----------|
| Issue                        |                              |          |
|                              |                              |          |
|                              | Issue visibility             |          |
|                              | <ul> <li>External</li> </ul> | ~        |
|                              | Subcategory                  |          |
|                              | ✓ Please select              | ~        |
| •                            | Subcategory is required      |          |
|                              |                              |          |
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#### Recommendations

It was difficult to find the Issue Management section.

| iii medidata                            |   |  |
|---|---|--|
|   |   |  |
|   |   |  |
| iMedidata now offers two                | -factor authentication as an additional security enhancement. Click here to learn more, |  |
|   |   |  |
| Apps                                    |   |  |
| RAVE<br>Rom                             | Studies (1)   |  |
| JanssenEDC1-Innovate                    |   |  |
| STUDY MANAGEMENT<br>Study Management    | 42847922MDD2002<br>Rave RCM<br>Study Management   |  |
| JanssenEDC1-Innovate                    | Stralegic Monitoring<br>Issue Management  |  |
| STRATEGIC MONITORING<br>Site Monitoring | Task Management<br>Dashboard<br>MEDS Reporter   |  |
| JanssenEDC1-Innovate                    |   |  |
| ISSUE MANAGEMENT<br>Issue Management    |   |  |
| JanssenEDC1-Innovate                    |   |  |
| TASK MANAGEMENT                         |   |  |
| Task Management                         |   |  |
| JanssenEDC1-Innovate                    |   |  |
| DASHBOARD                               |   |  |
| Dashboard                               |   |  |
| JanssenEDC1-Innovate                    |   |  |
| REPORTING                               |   |  |
| MEDS Reporter                           |   |  |



Rave RCM Study Management Strategic Monitoring Issue Management Task Management Dashboard MEDS Reporter

> And so here I am now I have to go to the issue management module which is easy to find here in all the options. So that's nice.







Recommendations

Increasing the minimum text size to 14px will help accessibility issues



Medidata: User Testing

Spacing elements to make the list more scannable.

Rave CRM

Study Management

Strategic Monitoring

Issue Management

Task Management

Dashboard

MEDS Reporter

### Recommendations

"How do I review it and close it out? I don't see the button to save."

Users noted they were unable to confirm changes through a save button



One of these button sets at the end of the form would be helpful



"I don't see a Save button. If I leave will it stay?"

Although the Status changed, users weren't confident their edits would be saved.



Leveraging existing patterns to reinforce user decisions (Snack-bars)

Global toggle for enabling Edit Mode/Save changes. On click all fields become editable, "Edit" Button becomes "Save" while edit mode is active





### Task Summary

### Testers: LTM, CTA, CTA







Task 1 - Add an Internal Team Member

#### Scenario:

Add yourself as an Internal Team Member to study 'CTMS\_EVAL\_UXUI2'

#### Add yourself as an Internal Team Member

Login to Innovate: https:// innovate.medidata.com/ and use the Study Management Module to add yourself as an Internal Team Member with the Role in Study as either 'Clinical Research Associate', 'Country Manager' or 'Study Manager.'

| 1. Ho<br>3 respo | w difficu |
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It or easy was it to complete this task?

| Chart | Data | Customize 🗸 | Export <b>v</b> |
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3 responses

Most popular words:

| An | Answers 3 |    |  |
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2. Please explain your rating.

Export 🗸

## nothave steps

Select one of the most popular words to see other words used in the same phrase

|  | 🗘 Copy sheet |
|--|--------------|
| Answer \$  | UZ_ID \$     |
| Steps are not fully explained to move forward  | C6091S114_36 |
| add yourself and a mate it is not easy, you have to take several steps.  | C6091S114_40 |
| It was no intuitive, where you can find the ootion, and the information that I have to update in CTMS is no clear.<br>I need to know my role, the country, in order to know where and how I have to update CTMS. | C6091S114_42 |



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Chart Data Customize 
Export



Task 2 - Add an External Site Contact

#### Scenario:

Imagine that you've been asked to add an external Site Contact to study 'CTMS\_EVAL\_UXUI2'.

#### **Add External Site Contact:**

Login to Innovate https:// innovate.imedidata.com/ and use the Study Management Module to add a 'Clinical Research Coordinator' to a site.







Task 2 - Add an External Site Contact

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3 responses

Most popular words:

| Ansv | Answers 3 |  |  |
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2. Please explain your rating.

Export 🗸

## nothave steps

Select one of the most popular words to see other words used in the same phrase

|  | 🗘 Copy sheet |
|--|--------------|
| Answer \$  | UZ_ID \$     |
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| add yourself and a mate it is not easy, you have to take several steps.  | C6091S114_40 |
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| 1. Effe<br>2 respo | ective |
|--------------------|--------|
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|          |               |
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|          | <b>0%</b> (0) |
| Success  | Non Success   |



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Chart Data



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Imagine that you've been asked to add an external Site Contact to study 'CTMS\_EVAL\_UXUI2'.

#### **Add External Site Contact:**

Login to Innovate https:// innovate.imedidata.com/ and use the Study Management Module to add a 'Clinical Research Coordinator' to a site.

| <b>4. (</b><br>2 re: | Clicks |
|----------------------|--------|
| 2                    |        |
| 1                    |        |
| 0                    |        |





Quality of Experience (Qx) Score

- 1 Strongly Disagree
- 2 Disagree
- 3 Neutral
- 4 Agree
- 5 Strongly Agree

1. Please rate your level agreement to the following statements about this website.

3 responses

The website is easy to use.

It is easy to navigate within this website.

The information on the website is credible.

The information on the website is trustworthy.

I find the website to be attractive.

The website has a clean and simple presentation.

I will likely return to the website in the future.





What we heard

It would be a good feature if I could find the member lists who were added to the study. Maybe it's available on the page but I wasn't very sure where to find it.

It was not intuitive, where you can find the option, and the information that I have to update in CTMS is not clear. I need to know my role, the country, in order to know where and how I have to update CTMS.

Adding yourself and a mate it is not easy, you have to take several steps. I wasn't sure if I successfully added the team member or not.



Recommendations

Direction was unclear for some users as to their next step upon landing on the "Manage Teams" page

"On the Manage Teams page I'm not really sure where I should click, probably the Quick Production page from the drop down?"



| 1            | studies                        | ACTIONS            |                  |            |          |          |        |                        |          |         |
|--------------|--------------------------------|--------------------|------------------|------------|----------|----------|--------|------------------------|----------|---------|
| 1-Innovate - | 42847922MDD2002 -              | Admin +            |                  |            |          |          | Help + | CTMS - CRA (Site Manaç | ger) + t | takahin |
|              | Manage                         | leams              |                  |            |          |          |        |                        |          |         |
| ies          | OVERVIEW +                     |                    |                  |            |          |          |        |                        |          |         |
|              | Select An Envir                | onment             |                  |            |          |          |        |                        |          |         |
|              |                                |                    |                  |            |          |          |        |                        |          |         |
|              |                                |                    |                  |            |          |          |        |                        |          |         |
|              |                                |                    |                  |            |          |          |        |                        |          |         |
|              |                                |                    |                  |            |          |          |        |                        |          |         |
| )            |                                |                    |                  |            |          |          |        |                        |          |         |
| 1-Innovate 👻 | studes<br>42847922MDD2002 -    | Actions<br>Admin + |                  |            |          |          | Help + | CTMS - CRA (Site Manaç | ger) + t | akahiro |
|              | Manage                         | Teams              |                  |            |          |          |        |                        |          |         |
| ies          | OVERVIEW                       |                    |                  |            |          |          |        |                        |          |         |
|              | Overview                       |                    |                  |            |          |          |        |                        |          |         |
|              | <ul> <li>Production</li> </ul> |                    |                  |            |          |          |        |                        |          |         |
|              |                                |                    |                  |            |          |          |        |                        |          |         |
|              |                                |                    |                  |            |          |          |        |                        |          |         |
|              |                                |                    |                  |            |          |          |        |                        |          |         |
|              |                                |                    |                  |            |          |          |        |                        |          |         |
|              |                                |                    | <b>Over View</b> | Production | Subnav 3 | Subnav 4 |        |                        |          |         |
|              |                                |                    |                  |            |          |          |        |                        |          |         |
|              |                                |                    |                  |            |          |          |        |                        |          |         |
|              |                                |                    |                  |            |          |          |        |                        |          |         |
|              |                                |                    |                  |            |          |          |        |                        |          |         |
|              |                                |                    |                  |            |          |          |        |                        |          |         |

Utilize a tabbed sub navigational pattern or loading a default screen instead of a drop-down



### Recommendations

#### Adding a filter to the list to display "Recently Added" will help users find the results they are after

| ≡medidata              | -                         |                    |                    |                    |   |
|------------------------|---------------------------|--------------------|--------------------|--------------------|---|
| JanssenEDC1-Innovate - | 42847922MDD2002 - Admin   |                    |                    | Help + C1          | TMS - CRA (Site Manager) + takahiro okazaki + |
| Marage Study           | Manage Tean               | ıs                 |                    |                    |   |
| Manage Countries       | PRODUCTION +              |                    |                    |                    |   |
| 🗄 Manage Sites         | Add Person to Study Teams | Export Teams       |                    |                    | Show Filter Y Search here Q                   |
| Manage Access          | Team                      | External/Internal  | Team Members       | Role in Study      | Oate  |
| A Manage Teams         | Study                     | Internal Personnel | Adam Bakata        | Study Manager      | 01-MAR-2021 - Present                         |
|                        | Study                     | Internal Personnel | Leanne Stone       | Study Manager      | 08-JUX-2021 - Present                         |
|                        | Study                     | Internal Personnel | Christine Mazzucco | Study Manager      | .3-AUG-2020 - Present                         |
|                        | Study                     | Internal Personnel | Adam Bakala        | Lead CRA (Primary) | 27-JUL-2021 - Present                         |
|                        | United States             | Internal Personnel | Christine Mazzucco | Country Menager    | 01-MAR-2021 - Present                         |
|                        | United States             | Informal Personnel | Adam Bakala        | Country Managor    | 01-JAN-2020 - Present                         |
| Show Fil               | ter T Re                  | ecently Added      | Members            | ٩                  |   |



User's indicated they would like to be able to view "Recently Added" members to the study.

It would be a good feature if I could find the member lists who were added to the study. Maybe it's available on the page but I wasn't very sure where to find it.

# **Monitoring Visit**

Site Management

### Task Summary

#### Testers: SM, SM, SM, LTM







Task 1 - Schedule the Monitoring Visit

#### Scenario:

Imagine that you've been asked to Plan and schedule the monitoring visit.

## Create an MVR and submit a report for review

Information you may need to complete task: Use the JanssenEDC1-Innovate study group Country Code - USA Site Number - 1001



1. How difficult or easy was it to complete this task?

|      |     |                            | Chart | Data | Customize 🛩 | Export 🛩 |
|------|-----|----------------------------|-------|------|-------------|----------|
|      |     |                            |       |      |             |          |
| 100% |     |                            |       |      |             |          |
| 100% |     |                            |       |      |             |          |
|      |     |                            |       |      |             |          |
|      |     |                            |       |      |             |          |
|      |     |                            |       |      |             |          |
|      |     |                            |       |      |             |          |
|      |     |                            |       |      |             |          |
|      |     |                            |       |      |             |          |
|      |     |                            |       |      |             |          |
|      |     |                            |       |      |             |          |
|      | 0%  | 0%                         | 0%    |      | 0%          |          |
|      |     | Very difficult — Very easy |       |      |             |          |
|      | • 1 | ● 2 <b>●</b> 3 ● 4 ● 5     |       |      |             |          |
|      |     |                            |       |      |             |          |



Task 1 - Scheduling the Monitoring Visit

#### Scenario:

Imagine that you've been asked to Plan and schedule the monitoring visit.

#### Create an MVR and submit a report for review

Information you may need to complete task: Use the JanssenEDC1-Innovate study group Country Code - USA Site Number - 1001 2. Please explain your rating.

4 responses

hart Data Customize 🖌 Export 🗸

Most popular words:



Select one of the most popular words to see other words used in the same phrase

| Answers 4 |  | 🗘 Copy sheet |
|-----------|--|--------------|
| # \$      | Answer \$  | UZ_ID \$     |
| 1         | I was not able to find the place to complete the task  | C6091S115_18 |
| 2         | Time zone was required per error code but could not save. Could not find an Add visit button for Study 42847922MDD2002 | C6091S115_30 |
| 3         | cannot identify how to plan a visit  | C6091S115_33 |
| 4         | Cannot complete as cannot save site time zone  | C6091S115_36 |



Task 1 - Scheduling the Monitoring Visit

#### Scenario:

Imagine that you've been asked to Plan and schedule the monitoring visit.

## Create an MVR and submit a report for review



Task 1 - Scheduling the Monitoring Visit

#### Scenario:

Imagine that you've been asked to Plan and schedule the monitoring visit.

#### **Create an MVR and submit a report for review**

| 2. Time<br>4 responses |  |
|------------------------|--|
| 250                    |  |
| 200                    |  |
| 150                    |  |
| 100                    |  |
| 50                     |  |
| 0                      |  |
|                        |  |
|                        |  |



Task 1 - Scheduling the Monitoring Visit

#### Scenario:

Imagine that you've been asked to Plan and schedule the monitoring visit.

#### Create an MVR and submit a report for review

| <b>4. (</b><br>4 re: | Clicks<br>sponses |
|----------------------|-------------------|
| 25                   |                   |
| 20                   |                   |
| 15                   |                   |
| 10                   |                   |
| 5                    |                   |
| 0                    |                   |
|                      |                   |
|                      |                   |
|                      |                   |



Task 2 - Completion of Visit Report

#### Scenario:

Imagine that you've been asked to Plan and schedule the monitoring visit.

#### **Create a Confirmation Letter**

Information you may need to complete task: Use the JanssenEDC1-Innovate study group Country Code - USA Site Number - 1001

| 1. Ho<br>4 respo | w diffic |
|------------------|----------|
| 100%             |          |
| 80%              | _        |
| 60%              |          |
| 40%              | _        |
| 20%              |          |
| 0%               |          |
|                  |          |

cult or easy was it to complete this task?

|      |     |                            | Chart | Data | Customize 🗸 | Export 🗸 |
|------|-----|----------------------------|-------|------|-------------|----------|
|      |     |                            |       |      |             |          |
| 100% |     |                            |       |      |             |          |
|      |     |                            |       |      |             |          |
|      |     |                            |       |      |             |          |
|      |     |                            |       |      |             |          |
|      |     |                            |       |      |             |          |
|      |     |                            |       |      |             |          |
|      |     |                            |       |      |             |          |
|      |     |                            |       |      |             |          |
|      |     |                            |       |      |             |          |
|      | 0%  | 0%                         | 0%    |      | 0%          |          |
|      |     | Very difficult — Very easy |       |      |             |          |
|      | • 1 | ● 2 <b>●</b> 3 ● 4 ● 5     |       |      |             |          |
|      |     |                            |       |      |             |          |



Task 2 - Completion of Visit Report

#### Scenario:

Imagine that you've been asked to Plan and schedule the monitoring visit.

#### **Create a Confirmation Letter**

Information you may need to complete task: Use the JanssenEDC1-Innovate study group Country Code - USA Site Number - 1001 2. Please explain your rating.

4 responses

Chart Data

ze 🗸 🛛 Export 🗸

Most popular words:



Select one of the most popular words to see other words used in the same phrase

| Answers 4 |  | Copy sheet   |
|-----------|--|--------------|
| # \$      | Answer \$  | UZ_ID \$     |
| 1         | not able to find the field in the system to complete the task  | C6091S115_18 |
| 2         | Could not update time zone per error message to schedule a visit. could not create letter without scheduled visit. | C6091S115_30 |
| 3         | Not an LTM task  | C6091S115_33 |
| 4         | Unable to create letter  | C6091S115_36 |
|           |  |              |
|           |  |              |

Task 2 - Completion of Visit Report

#### Scenario:

Imagine that you've been asked to Plan and schedule the monitoring visit.

#### **Create a Confirmation Letter**



Task 2 - Completion of Visit Report

#### Scenario:

Imagine that you've been asked to Plan and schedule the monitoring visit.

#### **Create a Confirmation Letter**

| 2. Ti  | ime    |
|--------|--------|
| 4 resp | oonses |
| 150    |        |
| 125    |        |
| 100    |        |
| 75     |        |
| 50     |        |
| 25     |        |
| 0      |        |
|        |        |
|        |        |
|        |        |



Task 2 - Completion of Visit Report

#### Scenario:

Imagine that you've been asked to Plan and schedule the monitoring visit.

#### **Create a Confirmation Letter**

| <ol> <li>Clicks</li> <li>4 responses</li> </ol> |  |  |  |  |
|---|--|--|--|--|
| 20  |  |  |  |  |
| 15  |  |  |  |  |
| 10  |  |  |  |  |
| 5   |  |  |  |  |
| 0   |  |  |  |  |
|   |  |  |  |  |
|   |  |  |  |  |



Task 3 - Review of Visit Report

#### Scenario:

Imagine that you've been asked to Plan and schedule the monitoring visit.

#### **Review and approve Visit Report**

Information you may need to complete task: Country Code - USA Site Number – 1002 Confirmation Letter, VR and FU Letter should be created for site 1001



1. How difficult or easy was it to complete this task?

|      |     |                            | Chart Da | ata Customize ~ | Export 🗸 |
|------|-----|----------------------------|----------|-----------------|----------|
|      |     |                            |          |                 |          |
| 100% |     |                            |          |                 |          |
|      |     |                            |          |                 |          |
|      |     |                            |          |                 |          |
|      |     |                            |          |                 |          |
|      |     |                            |          |                 |          |
|      |     |                            |          |                 |          |
|      |     |                            |          |                 |          |
|      |     |                            |          |                 |          |
|      |     |                            |          |                 |          |
|      | 0%  | 0%                         | 0%       | 0%              |          |
|      |     | Very difficult — Very easy |          |                 |          |
|      | • 1 | ● 2 ● 3 ● 4 ● 5            |          |                 |          |
|      |     |                            |          |                 |          |



Task 3 - Review of Visit Report

#### Scenario:

Imagine that you've been asked to Plan and schedule the monitoring visit.

#### **Review and approve Visit Report**

Information you may need to complete task: Country Code - USA Site Number – 1002 Confirmation Letter, VR and FU Letter should be created for site 1001

4 responses

| Answers 4 |   | 凸 Copy sheet |
|-----------|---|--------------|
| # \$      | Answer \$   | UZ_ID \$     |
| 1         | not able to find the field in the system  | C6091S115_18 |
| 2         | could not locate a visit report for review. unable to create VR, confirmation or follow up letter for site 1001   | C6091S115_30 |
| 3         | Instructions conflict. Could not create documents for review Information you may need to complete this task:<br>Country Code - USA Site Number – 1002 Confirmation Letter, VR and FU Letter should be created for site 1001 | C6091S115_33 |
| 4         | unable to create a report for review  | C6091S115_36 |
|           |   | 1            |

2. Please explain your rating. Export 🗸 Most popular words: unable letter 1001 could not create report site Select one of the most popular words to see other words used in the same phras review confirmation

Task 3 - Review of Visit Report

#### Scenario:

Imagine that you've been asked to Plan and schedule the monitoring visit.

#### **Review and approve Visit Report**

Information you may need to complete task: Country Code - USA Site Number – 1002 Confirmation Letter, VR and FU Letter should be created for site 1001

| 1. Effe<br>4 respo      | ectiv |
|-------------------------|-------|
| 100%                    |       |
| 75%                     |       |
| 50%                     |       |
| 25%                     |       |
| 0%                      |       |
|                         |       |
| 75%<br>50%<br>25%<br>0% |       |

![](_page_61_Figure_8.jpeg)

Task 3 - Review of Visit Report

#### Scenario:

Imagine that you've been asked to Plan and schedule the monitoring visit.

#### **Review and approve Visit Report**

Information you may need to complete task: Country Code - USA Site Number – 1002 Confirmation Letter, VR and FU Letter should be created for site 1001

| 2. T<br>4 resp | <ol> <li>2. Time</li> <li>4 responses</li> </ol> |  |  |  |  |
|----------------|--|--|--|--|--|
| 125            |  |  |  |  |  |
| 100            |  |  |  |  |  |
| 75             |  |  |  |  |  |
| 50             |  |  |  |  |  |
| 25             |  |  |  |  |  |
| 0              |  |  |  |  |  |
|                |  |  |  |  |  |
|                |  |  |  |  |  |
|                |  |  |  |  |  |

![](_page_62_Figure_8.jpeg)

Task 3 - Review of Visit Report

#### Scenario:

Imagine that you've been asked to Plan and schedule the monitoring visit.

#### **Review and approve Visit Report**

Information you may need to complete task: Country Code - USA Site Number – 1002 Confirmation Letter, VR and FU Letter should be created for site 1001

| <ol> <li>Clicks</li> <li>4 responses</li> </ol> |  |  |  |  |  |
|---|--|--|--|--|--|
| 8   |  |  |  |  |  |
| 6   |  |  |  |  |  |
| 4   |  |  |  |  |  |
| 2   |  |  |  |  |  |
| 0   |  |  |  |  |  |
|   |  |  |  |  |  |
|   |  |  |  |  |  |

![](_page_63_Figure_8.jpeg)

Quality of Experience (Qx) Score

- 1 Strongly Disagree
- 2 Disagree
- 3 Neutral
- 4 Agree
- 5 Strongly Agree

4 responses

The website is easy to use.

It is easy to navigate within this website.

> The information on the website is credible.

> The information on the website is trustworthy.

I find the website to be attractive.

The website has a clean and simple presentation.

> I will likely return to the website in the future.

![](_page_64_Figure_17.jpeg)

What we heard

I'm going to click on Site Monitoring.

Oh it's making me update the Timezone how do we find that.

It won't let me save the timezone.

Okay I met the site monitoring dashboa no items to display.

I do not understand how to schedule a visit.

|     | Click on my Protocol ID and click Visits.                                 |
|-----|---|
|     | Is there an FAQ section where I can read how to create a visit?           |
|     | Not sure how to add a visit because my site does not come up on the list. |
| ard | It won't let me update the time zone.                                     |

![](_page_65_Picture_10.jpeg)

### Recommendations

### Navigating to the task area was confusing for some

| 1 | ∎n         | nedidata               |                              |                              |              |              |      |
|---|------------|------------------------|------------------------------|------------------------------|--------------|--------------|------|
| 1 | 6          | JanssenEDC1-Innovate - | STUDIES<br>42847922MDD2002 - | ACTIONS<br>Site Monitoring - | Production + |              | H    |
| 0 | 5          | Overview               | Visits                       |                              |              |              |      |
| C |            | Visits                 | Study JanssenEDC1-Inr        | lovate                       |              |              |      |
| , | ¢          | Settings               |                              |                              |              |              |      |
| 4 | <u>;</u> . | Teams 🔻                | Visit ID                     | Visit Date                   | Conduct      | Visit Status | Repo |
|   |            |                        | There are no visit           | S.                           |              |              |      |
|   |            |                        | 0 Total Result(s)            |                              |              |              |      |
| < | C          | OLLAPSE                |                              |                              |              |              |      |

Reorganizing some of the information architecture could help users to find what they're looking for more quickly.

Grouping relevant areas will reduce search time.

Medidata: User Testing

![](_page_66_Picture_7.jpeg)

"Maybe I can find the section for a confirmation letter creation, no overview under production, maybe production. No."

"Not sure how to add a visit because my site does not come up on the list."

![](_page_66_Picture_11.jpeg)

### Recommendations

| Overview   | ▲ Study<br>for CTMS_EVAL | uxui   |           |                     |                         |
|------------|--------------------------|--|-----------|---------------------|-------------------------|
| Settings   | Site<br>Number           | Site Name  | Risk Tier | Visit<br>Scheduling | Risk t<br>last<br>updat |
|            | *<br>TST-DIA-<br>1001    | Baker Heart and Diabetes<br>Institute                                  | Medium 👻  | Manual 🔻            | Syste<br>15, 20         |
|            | TST-DIA-<br>1002         | Texas Diabetes and<br>Endocrinology- North Mopac                       | Medium    | Manual              | Syste<br>15, 20         |
|            | TST-DIA-<br>1007         | Pfutzner Science and Health<br>Institute Diabeteszentrum and<br>Praxis | Medium    | Manual              | Syste<br>15, 20         |
| < COLLAPSE | TST-DIA-                 | Diabetes and Endocrine   |           |                     | Syste                   |

Backend error notification when user attempts to save the changes and complete the task.

"Study site settings maybe in there. Okay, click on the pencil. Please select time zone. Oh here we go."

| tier            | Site time zone | Site Baker Heart and     Diabetes Institute co     be saved | d<br>auld not |
|-----------------|----------------|---|---------------|
| em, Jul<br>2021 | (GMT-10:00) F  | Honolulu × 🔻  | < x           |
| em, Jul<br>2021 | Please select  | ۲   | 1             |
| em, Jul<br>2021 | Please select  |   | /             |
| em. Jul         |                |   |               |

After locating the task area, the users were unable to complete the task.

# Thanks for reading!

![](_page_68_Picture_1.jpeg)