REDCap's Linear Data Entry Workflow (LDEW) External Module: Introduction and Guide to Setting It Up in your Project

Note: there is a $100 one-time fee to activate this module in each REDCap project. This fee does not include setting up the LDEW form exceptions or configuring the module for your project. There is a $100/hour fee if you would like the REDCap Team to configure the module for your project's needs.

Introduction:

The LDEW external module forces a linear data entry workflow across REDCap forms and events by removing access to any form which does not immediately follow the last completed form. For example, if a user has not filled out the first form, they cannot proceed to the second (or/and subsequent) forms. However, you can list form exceptions to the LDEW for any form that will not be able to be completed in sequential order. In a typical clinical research workflow form collecting laboratory values might be listed as an exception, since these values might not be obtained until after the visit is completed. The LDEW module also prevents users from marking a form as 'Complete' if any of the required fields on a form are blank, thereby blocking access to the next form until all required fields have data in them. Additionally, LDEW can be configured to automatically lock forms upon completion for certain user roles. These roles will **not** have the ability to unlock these forms on their own – a user that is not in the auto-locking role, and has record locking/unlocking privileges will need to unlock the forms if data changes need to be made.

This module can be configured at the project level to exclude some forms from these rules and to make each event independent from the others. This second feature is useful if there are events in the project that are not linear. In a typical clinical research workflow, events for recording adverse events or unexpected visits, could occur at any time point during the study.

Data Entry Workflow using the LDEW Module:
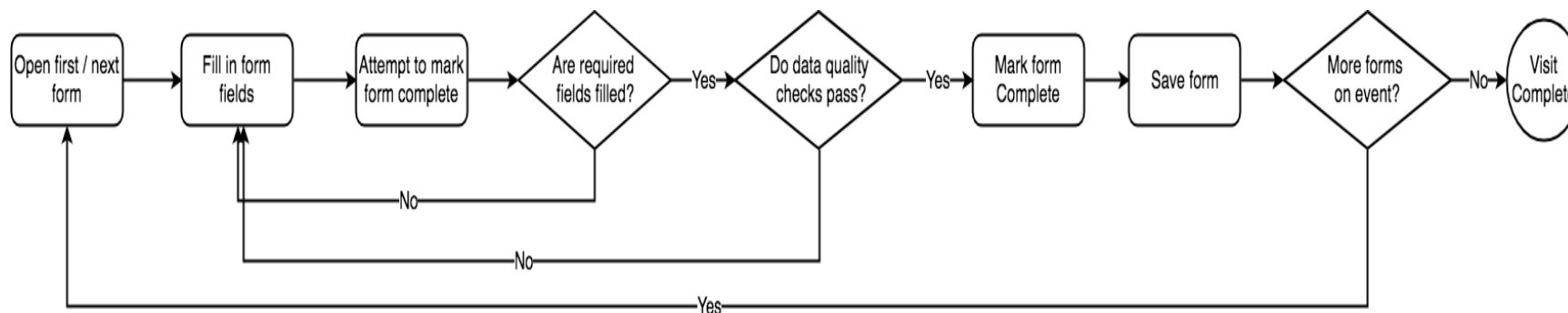
Some use cases of LDEW include:

- Forcing data entry staff to fill out forms in sequence to ensure data collection forms are not skipped.
- Enforcing a form's required field(s) to be filled out before moving to the next form or before marking the form as 'Complete'. Normally, required fields are only strictly enforced on forms completed as surveys.
- Requiring a form to be marked '*Complete*' to be able to move on to the next form.
- 'Auto-locking' of forms once they are marked as 'Complete' to ensure data is not later modified or deleted.

Requirements to Use/Configure the Module:

- A REDCap project with *multiple* data collection forms/surveys.
- The User Right of 'Project Design and Setup."
- User Roles defined if using the auto-locking feature.
- Provide the REDCap Team with your fiscal contact information for the $100 activation fee (to be billed upon module activation).

Features Included:

1) Reveal Forms in Order (RFIO)

This feature operates under the assumption that only complete forms and the immediately ensuing non-complete form should be accessible. For this module, complete is indicated by selecting "Completed" from the completion dropdown. For example, if you have 3 forms, X, Y, and Z - in that order, and only form X has been completed, then the user can access form X and form Y, but not form Z. Form Z will become available after form Y is complete.

This feature changes REDCap's behavior on 3 pages when entering data:

1. **Record Status Dashboard**: Ensures the record status dashboard only reveals forms that should be accessible. It goes through each record, and disables links to all forms that are not marked as Complete or immediately following a completed form. If there are multiple events, forms are evaluated one event at a time, with the assumption that each event must be completed before any forms on the next event can be accessed.
2. **Record Home**: Performs much the same function as described above, but on an individual record's home page. This means that each event is evaluated separately, and the form immediately ensuing the last complete form is the last accessible form.
3. **Data Entry Form**: Prevents users from using the left-hand sidebar links to navigate to forms that should be inaccessible.

In the example below, there are no form exceptions, so all forms and events must be filled out sequentially.

Data Collection Instrument	Enrollment	Visit 1	Visit 2	Visit 3	Final visit
Informed Consent	●				
Demographics	○ ⬅				
Cancer Screening	○				
Chart review	○				
Concomitant Medications	○	○	○	○	○
Comorbidities	○				
Pain Assessment And Documentation Tool	○		○		○
Labs	○	○	○	○	
Adverse Events		○	○	○	○

Data Collection Instrument	Enrollment	Visit 1	Visit 2	Visit 3	Final visit
Informed Consent	●				
Demographics	● 🔒				
Cancer Screening	○ ⬅				
Chart review	○				
Concomitant Medications	○	○	○	○	○
Comorbidities	○				
Pain Assessment And Documentation Tool	○		○		○
Labs	○	○	○	○	
Adverse Events		○	○	○	○

Note that the *Cancer Screening* form does not become accessible until the previous form, *Demographics*, has been marked as Complete.

Data Collection Instrument	Enrollment	Visit 1	Visit 2	Visit 3	Final visit
Informed Consent	●				
Demographics	●				
Cancer Screening	●				
Chart review	●				
Concomitant Medications	●	○			
Comorbidities	●				
Pain Assessment And Documentation Tool	●		○		○
Labs	●	○	○	○	
Adverse Events		○	○	○	○

First form due at Visit 1 (event 2)

Note that the first form due at Visit 1, *Concomitant Medications*, is not accessible until **all** forms due at the Enrollment Event are marked as Complete.

2) Force Data Entry Constraints (FDEC)

This feature prevents users from marking a form as complete if the required fields are not filled in. Additionally, field verifications must be satisfied before the form can be marked as Complete.

For example, if the field 'Age' requires a number from 0 to 99 and the user enters 'fifty' (which is not a number) the form cannot be marked as complete. If the user attempts to mark the form complete with an empty field or unverified field, a popup window will direct them to the field(s) that need to be adjusted before they can mark the form complete.

3) Suppressing "Save & Go to Next Record"

In a clinical data collection workflow, the study coordinator is likely working with only one research participant at a time. In this case, the "Save & Go to Next Record" button might be a distraction. This button can be hidden via the modules project-level configuration option *Hide "Save & Go to Next Record" button*.

Save options when not using the feature: Save options when using the feature:
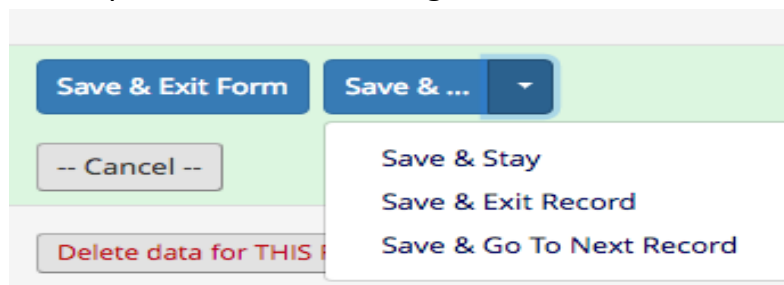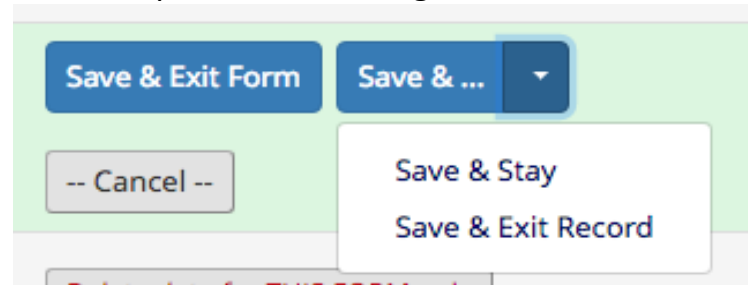
4) Auto-locking forms
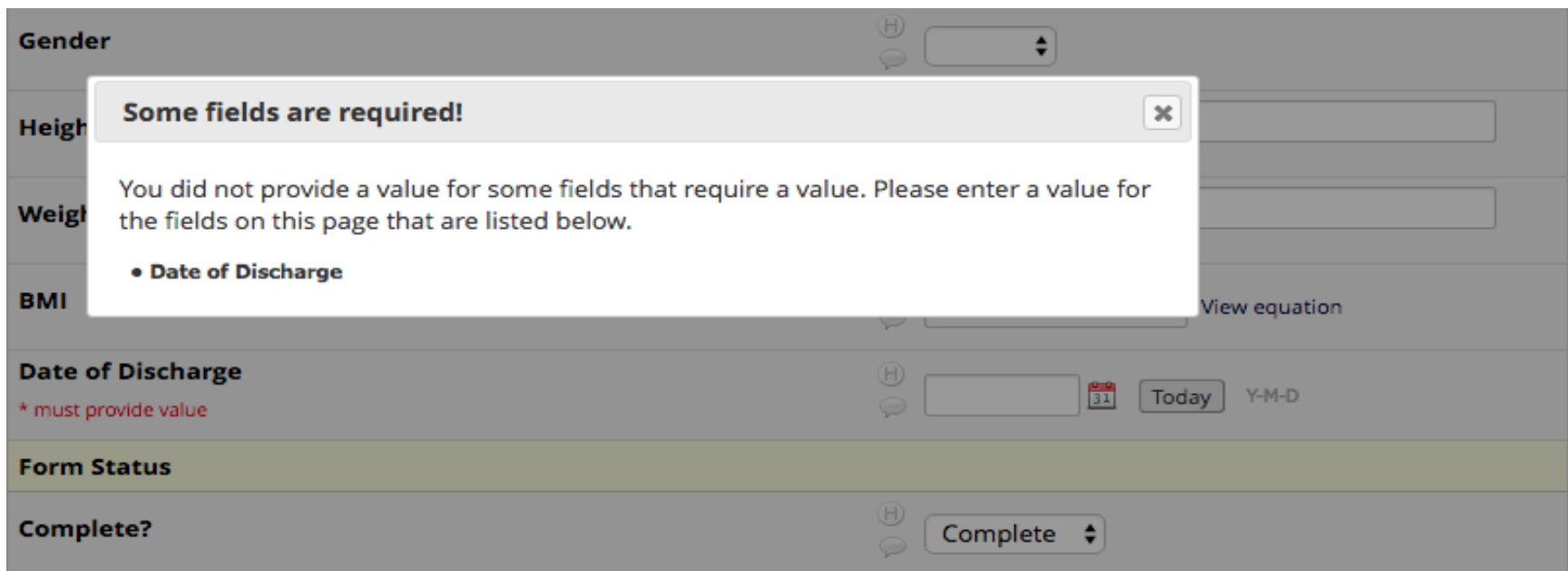
Linear Data Entry Workflow can be configured to automatically lock forms upon completion for certain user roles. These roles will not have the ability to unlock these forms on their own. For this feature to work properly the role must have Lock/Unlock privileges.

This can be configured in the **User Rights** page. To activate this feature, access **Manage External Modules** section of your project, click on Linear Data Entry Workflow's configure button, and select a role to activate auto-locking on.

Required Fields and LDEW

Using the LDEW module, if a user tries to mark a form as 'Complete' when it is missing data in a required field, the module will not allow them to mark the form as Complete and will not allow them to advance to the next form. Data must be entered in all the required data fields before the next form can be accessed.
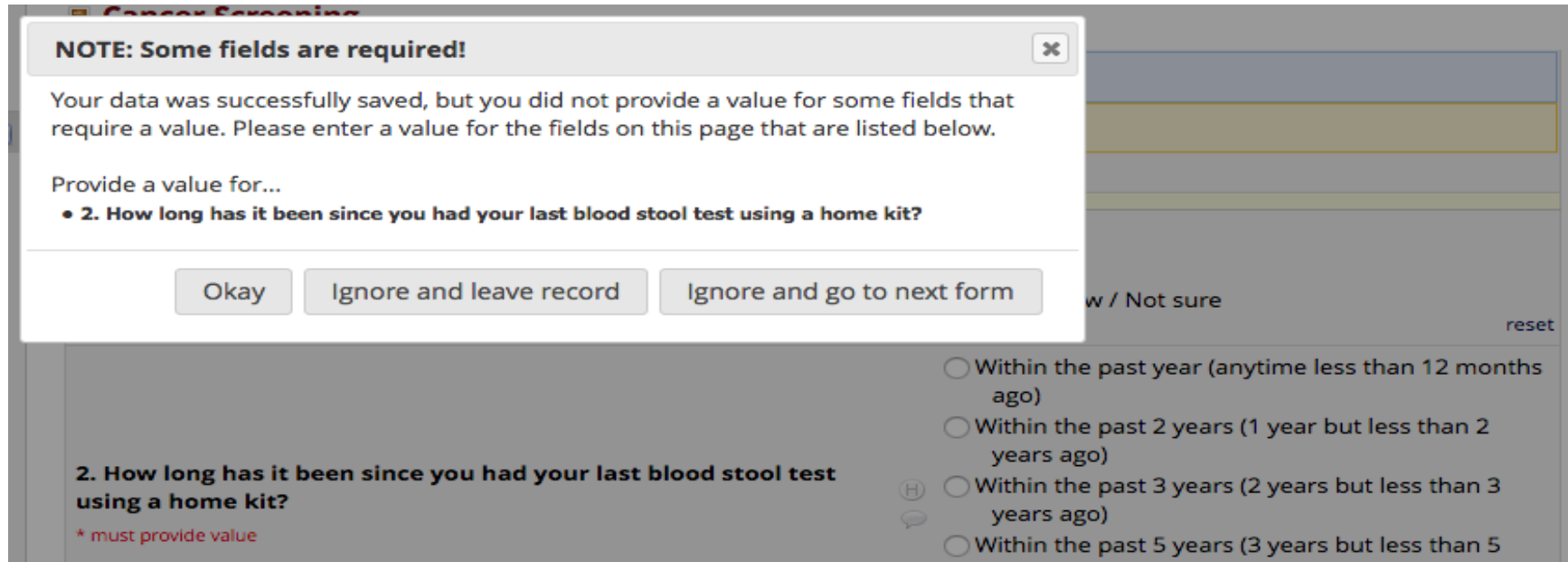
View of form save using LDEF when a required field has not been filled in:

Note that the usual "Okay", "Ignore and leave record", and "Ignore and go the next form" buttons are not presented (see next page), thereby forcing the person to enter data into these fields before they can move on.

View of form save *not* using LDEF when a required field has not been filled in:

Note that the [Okay], [Ignore and leave record], and [Ignore and go to next form] buttons are not available when using this module.

Steps to enable and use the LDEW Module:

1) Build all your project's data collection forms and data fields.
2) Assign all forms to study events (if project is longitudinal).
3) Contact the REDCap Support Team to enable to module (CTSI-REDCAP-SUPPORT-L@LISTS.UFL.EDU) and provide your fiscal contact information in the email for the $100 activation fee.

4) Once activated by the REDCap Support Team, click on the 'External Modules' link under the *Applications* menu in the project.
5) Click on 'Configure' next to the *Linear Data Entry Workflow*.
6) Configure the module.
7) Click on 'Save.'
8) Test the project's LDEW configuration using test data.
9) Request to move the project into Production status.
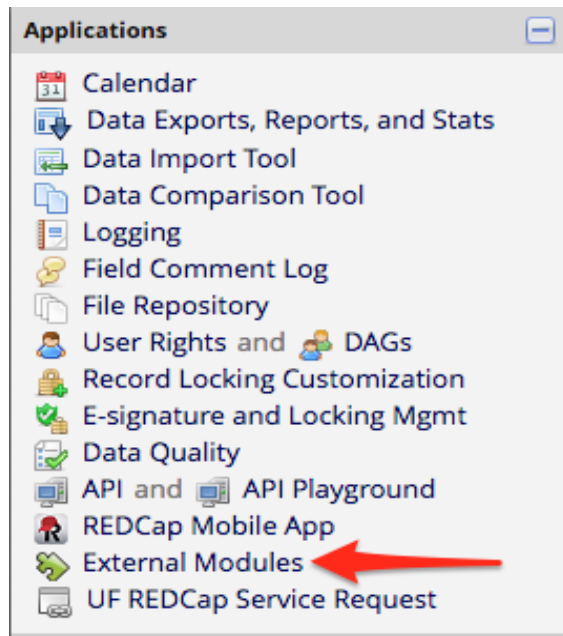
Note: you will need the User Right of 'Project Design & Setup' to have access to the External Modules page to configure the module.

Linear Data Entry Workflow - v2.5.1 `Discoverable`
This module forces a linear data entry workflow across REDCap forms and events. Forms must be filled from top to bottom and left to right. All required fields must be filled and the form's _Completed?_ status must be set to _Complete_ before the next form is made accessible. See the **documentation** at https://github.com/ctsit/linear_data_entry_workflow

Configure

Disable

📄 View Documentation

When you click on the Configure button, you will be taken to the screen shown below, where you will set up the LDEW form exceptions (if applicable), auto-locking roles (optional), and whether to allow events to be filled out non-sequentially (optional).

Configure Module: Linear Data Entry Workflow ✕

Project Settings	Value	
1. Forms Exceptions:	⬍	+
1. auto-locked roles:	⬍	+
Allow events to be filled out independently from each other:	☐	
Hide "Save & Go To Next Record" button:	☐	

Cancel   Save

Forms Exceptions: These are forms that you do NOT want to be included in LDEW. For example, if lab results are not known at the time of data collection, you would want to include the Labs form in the form exceptions so that it can be filled out later, thereby not impeding further data collection at that event. To add more than one form exception, click on the [+] next to the "Forms Exceptions" dropdown list.


In the configuration example above, the forms called 'Labs' and 'Chart Review' will be excluded from LDEW. As such, they are accessible at any time, even when all previous forms are not marked as Complete.

Record Home Page View:

Data Collection Instrument	Enrollment	Visit 1	Visit 2	Visit 3	Final visit
Informed Consent	⊙				
Demographics	⊙				
Cancer Screening	⊙				
Chart review	⊙				
Concomitant Medications	⊙	⊙	⊙	⊙	⊙
Comorbidities	⊙				
Pain Assessment And Documentation Tool	⊙		⊙		⊙
Labs	⊙	⊙	⊙	⊙	
Adverse Events		⊙	⊙	⊙	⊙

Note that both the *Chart Review* and *Labs* forms are excluded from the LDEW and can be accessed at any time. They would not need to be marked as 'Complete' to complete the Enrollment visit.

Data Collection Instrument	Enrollment	Visit 1	Visit 2	Visit 3	Final visit
Informed Consent	◉				
Demographics	○				
Cancer Screening	○				
Chart review	○				
Concomitant Medications	○	○	○	○	○
Comorbidities	○				
Pain Assessment And Documentation Tool	○		○		○
Labs	○	○	○	○	
Adverse Events		○	○	○	○

Note that since the *Informed Consent* form is marked as 'Unverified' (yellow), the next form, *Demographics*, is not accessible.

Data Collection Instrument	Enrollment	Visit 1	Visit 2	Visit 3	Final visit
Informed Consent	●				
Demographics	●				
Cancer Screening	●				
Chart review	●				
Concomitant Medications	●	●	○	○	○
Comorbidities	●				
Pain Assessment And Documentation Tool	●		○		○
Labs	●	○	○	○	
Adverse Events		○	○	○	○

Note that since *Labs* is a form exception, it does not have to be marked as Complete (green) to access the rest of the forms.

Auto-locked roles: If you would like forms to be automatically locked after the form is saved, so that no further data entry can occur on that form, select the user role(s) that you would like to enforce this on. <u>Note</u>: the users in this role will not be able to unlock the forms, even if they have the user right to Lock/Unlock forms. This is a feature of the LDEW module. A project user who is not in one of the auto-locking roles and has record locking/unlocking privileges will need to unlock the forms if further data entry is needed. Note: only Roles can be used for this feature, not individual user rights. If no roles are setup, you will not be able to use this feature.

On the User Rights page, create a Role or Roles that you can then assign users to. This role needs to have Record Lock/Unlock privileges, but they will not be able to unlock a form.

When someone in that role enters data, the forms are automatically locked when the form is saved:

Data Collection Instrument	Enrollment	Visit 1	Visit 2	Visit 3	Final visit
Informed Consent	🟢				
Demographics	🟢🔒				
Cancer Screening	🟢🔒				
Chart review	🟢🔒				
Concomitant Medications	🟢🔒	⚪	⚪	⚪	⚪
Comorbidities	🟢🔒				
Pain Assessment And Documentation Tool	🟢🔒		⚪		⚪
Labs	🟢🔒	⚪	⚪	⚪	
Adverse Events		⚪	⚪	⚪	⚪

Allow events to be filled out independently from each other:

You will need to enable this feature if events can be filled out non-linearly. In the example below, there are 5 visits that every subject will have – Enrollment, Visit 1, Visit 2, Visit 3 and Final Visit – and 2 visits that are as needed – Unexpected Visit 1 and Unexpected Visit 2. Not every subject will have unexpected visits. There's also an Adverse Event form, tied to its own event, since adverse events can occur at any time point in the study.

Data Collection Instrument	Enrollment (1)	Visit 1 (2)	Unexpected visit (3)	Visit 2 (4)	Unexpected visit 2 (5)	Visit 3 (6)	Final visit (7)	Adverse Events (8)
Informed Consent	✔							
Demographics	✔							
Cancer Screening	✔		✔		✔			
Chart review	✔							
Concomitant Medications	✔	✔	✔	✔	✔	✔	✔	
Comorbidities	✔							
Pain Assessment And Documentation Tool	✔		✔	✔	✔		✔	
Labs	✔	✔	✔	✔	✔	✔		
Adverse Events								✔

If the independent events feature was not enabled for this project, a user would have to fill out and complete all forms in the Unexpected Visit 1 event (the next event after Visit 1) to access the Visit 2 event forms. However, since not all subjects will have an Unexpected Visit, this data does not need to be collected for all subjects. Instead, you'd want the data entry staff to be able to *skip over* the Unexpected Visit event and go to the Visit 2 event. Also, because the 'Adverse Event' event is the last event in the project, the Adverse Event form would not become accessible until all forms were marked as complete in each previous event.

Note that the forms for Visit 2 cannot be accessed until all the forms for the Unexpected Visit event are completed if the 'Allow events to be filled out independently from each other' feature is not enabled:

Data Collection Instrument	Enrollment	Visit 1	Unexpected visit	Visit 2
Informed Consent	●			
Demographics	●			
Cancer Screening	●		○	
Chart review	●			
Concomitant Medications	●	●	○	○
Comorbidities	●			
Pain Assessment And Documentation Tool	●		○	○
Labs	●	●	○	○
Adverse Events				

However, when you check the option to allow events to be filled out independently from each other, you can now access the first form in every event and the Adverse Event form, which is in the last event.

Data Collection Instrument	Enrollment	Visit 1	Unexpected visit	Visit 2	Unexpected visit 2	Visit 3	Final visit	Adverse Events
Informed Consent	●							
Demographics	●							
Cancer Screening	●		○		○			
Chart review	●							
Concomitant Medications	●	○	○	○	○	○	○	
Comorbidities	●							
Pain Assessment And Documentation Tool	●		○	○	○		○	
Labs	●	○	○	○	○	○		
Adverse Events								○

Questions? Contact the REDCap Support Team at: https://redcap.ctsi.ufl.edu/redcap/surveys/?s=DUPrXGmx3L