

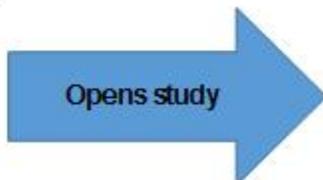
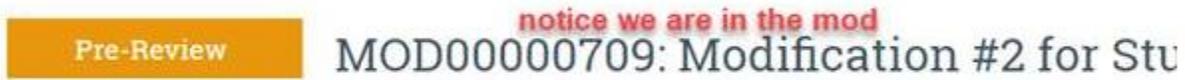
## Tip Sheet 5: Navigating UVMClick and Other Information

### 1. Navigating Tips

- **How do I find the parent study when I am in a modification?**

From the modification page, use the “breadcrumbs” feature to find your way back to the parent.

Click here, then here on the title



- **How do I get back to a modification from the parent study?**

On the parent study page, click on Follow-on Submissions. There you will see all your previous submissions. From the state you can tell if you have not submitted it yet (pre-submission), whether RPO has it (pre-review), or if it is approved.

History Funding Contacts Training Documents **Follow-on Submissions** Reviews Snapshots

Filter by ID Enter text to search for Add Filter Clear All

ID	Name	Date Modified	Owner	State	RB Coordinator
MOD00000711	Modification #5 for Study MonarchE-13Y-MC-JPCF-A Randomized, Open-Label, Phase 3 Study of Abemaciclib combined with Standard Adjuvant Endocrine Therapy versus Standard Adjuvant Endocrine Therapy Alone in Patients with High Risk, Node Positive, Early Sta	12/20/2018 2:44 PM		Pre-Submission	
MOD00000702	Modification #4 for Study MonarchE-13Y-MC-JPCF-A Randomized, Open-Label, Phase 3 Study of Abemaciclib combined with Standard Adjuvant Endocrine Therapy versus Standard Adjuvant Endocrine Therapy Alone in Patients with High Risk, Node Positive, Early Sta	12/20/2018 11:57 AM	Crain, Karen Ion	Pre-Review	Karen Crain
MOD00000400	Modification #3 for Study MonarchE-13Y-MC-JPCF-A Randomized, Open-Label, Phase 3 Study of Abemaciclib combined with Standard Adjuvant Endocrine Therapy versus Standard Adjuvant Endocrine Therapy Alone in Patients with High Risk, Node Positive, Early Sta	12/13/2018 3:22 PM	Crain, Karen Ion	Approved	Karen Crain
MOD00000367	Modification #2 for Study MonarchE-13Y-MC-JPCF-A Randomized, Open-Label, Phase 3 Study of Abemaciclib combined with Standard Adjuvant Endocrine Therapy versus Standard Adjuvant Endocrine Therapy Alone in Patients with High Risk, Node Positive, Early Sta	12/6/2018 1:21 PM	Thompson Nicholas Yves	Approved	Nicholas Thompson
MOD00000097	Modification #1 for Study MonarchE-13Y-MC-JPCF-A Randomized, Open-Label, Phase 3 Study of Abemaciclib combined with Standard Adjuvant Endocrine Therapy versus Standard Adjuvant Endocrine Therapy Alone in Patients with High Risk, Node Positive, Early Sta	11/30/2018 4:53 AM	Crain, Karen Ion	Approved	Karen Crain

## 2. Data Safety and Monitoring Reports or Non-Risk Safety Reports

Sponsors look for a descriptive comment about what was reviewed by the IRB. Below is a model example of a description that you would put in the summary of the modification for all DSMB and Non-Risk Safety Report.

### Modification Information

Study enrollment status (if applicable, check all that apply):

Subjects are currently enrolled

Notification of subjects: (if applicable, check all that apply)

There are no items to display

#### \* Summarize the modifications:

Submission includes: 1) QP ExCELS 12 Month Interim Post Approval Registry Report dated 01 November 2018 and 2) QP ExCELS MPP Sub-Study 18 Month Post-Approval Registry Report dated 02 November 2018

## 3. New Protocol and Clarification Responses

There are two different sections within the SMART form to upload documents. It is important that you upload the correct documents in each section. Below are the two areas:

**Protocol is uploaded under Study, #11.**

11. \* Attach the protocol: (e.g. industry protocol, human subjects protocol, exempt form, or not human subjects protocol) **Note: other attachments such as consent form and recruitment materials will be uploaded in a separate section**

Document	Category	Date Modified	Document History
131-AC-IPCF_MerandE_Protocol v 6/29/18(0.01)	IRB Protocol	12/20/2018	History

**Consent and Other Attachments are uploaded under Local Site Documents, #1, 2, &3.**

**Local Site Documents**

1. **Consent forms:** include an HHS-approved sample consent document, if applicable

Document	Category	Date Modified	Document History
Continue or Decline consent(1)	Consent Form	12/10/2018	History
UVM Consent 05Oct2018(1)	Consent Form	12/10/2018	History

2. **Recruitment materials:** add all material to be seen or heard by subjects, including ads

There are no items to display

3. **Other attachments:** (The Data Management Form is required)

**Data Form Required for every Protocol**

Document	Category	Date Modified	Document History
study team meeting checklist(0.01)	Supporting Document	12/17/2018	History
data management form(0.01)	Data Management Form	12/10/2018	History
budget compliance form(0.01)	Supporting Document	12/10/2018	History
request to rely form(0.01)	Supporting Document	12/10/2018	History
Consent Process with LAR(0.01)	Supporting Document	12/10/2018	History

**4. Updating/Revising Your Protocol Document**

When you need to revise your protocol, please make sure that you are “**updating**” the protocol document that is already present in the system. There should only be one protocol document in the system. When you click “**update**” the system will version the document behind the scenes. When you update, you should make sure that you include the version date on both the protocol document itself as well as the document name. This will ensure consistency.

12. \* Attach the protocol: (e.g. industry protocol, human subjects protocol, exempt form, or not human subjects protocol) **click here only when adding a NEW document to the submission**

Document	Category
test protocol(0.01)	IRB Protocol

**click here when revising a document**

**5. Printing Your Approved Documents**

In follow up to our last tip sheet regarding printing approved documents, the stamp is set very high on the page to avoid overwriting text within the document. We are looking into placing the stamp a little lower on the page, so we suggest that you allow for a 1-inch margin at the top of your documents. Hopefully this should resolve most printing issues. **Use of the stamped versions of consents and information sheets is required.**

