Protocol Fields Required in OnCore to Push/Create an eBinder

The already required fields must always be entered (either by study staff or OnCore support staff) to create the protocol shell. In addition, on the PC Console>Main>Details tab the Short Title is required. Short title cannot contain these characters [? " : | < > \ /]

Fields required for a push to Florence

★ Already required fields

Details	Management	Staff	Sponsor	IND/IDE	ClinicalTrials.gov / CTRP

Protocol Details — History

★ Protocol No.	FLORENCE-TEST-1	NCT Number	Search for Calendar
★ Library	Oncology	★ Department	Medicine / Hematology and Oncology
★ Organizational Unit	Cancer Center		
★ Title	Full Protocol Title Should Always Be Copy/Pasted Into This Field		
Short Title	Florence Test Protocol #1		
Objectives			

Phase		Scope		Age	Adults	Consent at Age of Majority	N/A
Drug Accountability		★ Investigator Initiated Protocol	No	Involves Therapy		Exclude Protocol on Web	No
Open For Affiliates Only		Summary Accrual Info. Only		★ Protocol Type	Supportive Care	
Cancer Control		Cancer Prevention		Data Table 4 Report Type		
Registration Center		Involves Correlates or Companions		Data Monitoring		Adjuvant
Includes Specimen Banking?	No	Companion Study?	No	Multi-site Trial		★ Investigational Drug	No
Precision Trial		Precision Trial Classification		Pilot		★ Investigational Device	No
Rare Disease						

Accrual Information

★ Protocol Target Accrual	500	RC Total Accrual Goal (Lower)	10	★ RC Total Accrual Goal (Upper)	10
RC Annual Accrual Goal		Affiliate Accrual Goal	10	★ Accrual Duration (Months)	24

Completion Dates

★ Primary Completion Date	09/02/2022
Study Completion Date	

Update

PC Console>Main>Management Tab. A Management Group is required to be entered to push an eBinder. Management groups of Biospecimen Management, CRI and Community Engagement will NOT push over to eBinders.

Fields required for a push to Florence

★ Already required fields

Details	**Management**	Staff	Sponsor	IND/IDE	ClinicalTrials.gov / CTRP

Management Details   History

IRB No.		Pharmacy No.		Priority Score		Enable Payments Integration	
SRC No.		SRC Review Required	No	DSMC Review Frequency (months)			
★ TRU Participation	No	TRU No.		TRU Approval Date		TRU Category	
PDQ No.		NCI Trial ID		CTMS Export	No		
Comments							
Coding Scheme	CTCAE v5.0	Generate MRN	No	Automated Sequence No.	No	Use Randomization Algorithm	
Internal Account No.		Hospital Account No.		Allow Duplicate Enrollment?	No		
Allow On Treatment date to be entered before On Study date	No	Populate On Follow-Up Date with Off Treatment Date	No				

Administrative Groups

Program Areas	Status		Oncology Group		★ Management Group	
No information entered			No information entered		Sarcoma	

Flowchart

Flowchart	Path
No information entered	

Update

PC Console>Institution Tab requires a Participating Institution to be entered to push to Florence.
Only studies being completed at MCW will be able to push to Florence.

Fields required
for a push to
Florence

★ Already
required
fields

Participating Institutions											
Institution • Study Sites	Uses Research Center IRB	IRB Initial Approval Date	IRB Last Renewal Date	IRB Next Review Date	Current Status	Status Date	Total Accrual	Pending Amendment	Expired Items	Calendar Version
Medical College of Wisconsin		09/08/2021	09/08/2021	09/14/2021	OPEN TO ACCRUAL	09/08/2021	0		Item	0

Pending Amendments   View PDF

Participating Networks
No information entered

Update

PC Console>Annotation tab contains the question used to push the protocol to Florence (Q1). Navigate to PC Console>(Choose Protocol)>Annotations. If Annotation Form already has been added you need to click the Update button.

★ PC Console   ?

Protocol No.: SURG-BOLTON-RELAY-PRO-D Library: MCW General   PI: Rossi, Peter   Sponsor: Bolton Medical

Protocol Target Accrual: 80   Accrual To Date: 3   Protocol Status: OPEN TO ACCRUAL

RC Total Accrual Goal (Upper): 10   IRB Expiration: 01/13/2022

1) Select Protocol

Select Protocol

SURG-BOLTON-RELAY-PRO-D ▾

Main	»
Treatment	»
Institution	
Accrual	
Status	»
Reviews	»
Documents/Info	»
Eligibility	
Notifications	
Annotations	
Deviations	
New Protocol	

Fields required for a push to Florence

1. Create study eBinder?

○ Yes

○ No

2. Sponsor eBridge Type

○ Federal

○ Federal Pass-Through

◉ For Profit

○ Not for Profit

○ State

○ Local

○ Internal

○ Children's Research Institute

3. Date Protocol Received by the Study Team

11/05/2019

4. Date Draft Contract received by the PI/Study Team

11/05/2019

5. Date Contract Fully Executed

05/15/2020

6. National Accrual - Overall national accrual at the time of entry

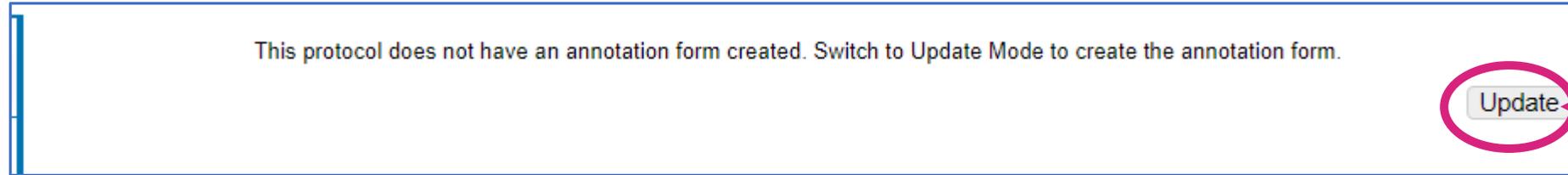7. National Accrual Date - enter t tab for todays date

Update

2) Click Update

If the Annotation form is not yet created, click the Update button to attach the Annotation to the protocol.

This protocol does not have an annotation form created. Switch to Update Mode to create the annotation form.
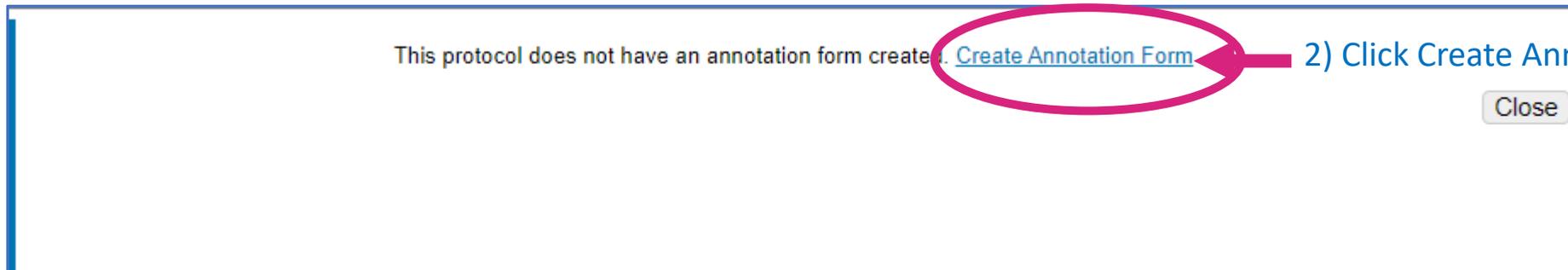
Update ⟵ 1) Click Update

Then click the Create Annotation Form hyperlink to add the Annotation form to the protocol.

This protocol does not have an annotation form created. Create Annotation Form ⟵ 2) Click Create Annotation Form

Close

If an eBinder should be created answer question 1 as Yes. Click **Save** after answering the question and confirm successful SAVE in the green banner. Click Close to exit. **IMPORTANT:** Protocols will only be pushed to eBinders if the protocol status was entered as New within 31 days of the push.

Success! Form saved. ← 2) Message received after form saved successfully.

✔ Save ← 1) Click Save after question(s) are answered

1. Create study eBinder?

- ⦿ Yes
- ○ No

2. Sponsor eBridge Type

- ○ Federal
- ○ Federal Pass-Through
- ○ For Profit
- ○ Not for Profit
- ○ State
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6. **National Accrual** - Overall national accrual at the time of entry

7. **National Accrual Date** - enter t tab for todays date

Close

✔ Save ← 1) Click Save after question(s) are answered