

Forms **ARE NOT** completed by clicking the hyperlink in the subject calendar. Rather, data entry is done through the Forms by Status in either the CRA or Subject Consoles.

Procedure	Treatment											
	Screening 2@1Days	Treatment 2,16,58,100@1Days				Open Label 3,5,8,11,14@1Months					Discontinuation 30@1Days	Post-Study 30@1Days
	1	2	3	4	5	6	7	8	9	10	11	12
Planned Date	08/01/2017	08/06/2017	08/20/2017	10/01/2017	11/12/2017							
Visit Status	V1 (-8wks)	V2 Dy 1	V3 2wks	V4 8wks	V5 14wks	V6 v5+1mth	V7 v5+3mth	V8 v5+6mth	v9 v5+9mth	v10 v5+12mth	D30	D30
Visit Date												
Informed Consent		X										
Medical History Review		X										
Physical Examination	PE-001 V1	X	X									
Concomitant Medication Review	T_CONMED V1	X	X	X	X	X	X	X	X	X		
Vital Signs	VITALS_Blood Pressure V1	X	X	X	X	X	X	X	X	X	X	X
Adverse Event Assessment	AE-001 V1	X	X	X	X	X	X	X	X	X	X	X
Drug Administration	SDA-001 V1	X	X	X	X	X	X	X	X	X		
QOL Questionnaires	QSTNR_QOL_BCTOS V1	X	X			X					X	X

Forms by Status

CRA Console
 Protocol No.: NEURO-EVANS-FEVERFEW
 Protocol Target Accrual: 400
 RC Total Accrual Goal (Upper): 10
 Short Title: Feverfew

In the **CRA Console**, the Forms by Status shows all forms for all subjects. Clicking on the column header will sort by Last Name, Visit, Procedure, etc.

Protocol Status
IRB #

Select Protocol	Quarantined Forms	To Do Forms	Active Forms	Completed Forms	Planned Forms	Forms Summary																																	
12345	<table border="1"> <thead> <tr> <th>Form No.</th> <th>Form Desc.</th> <th>Visit Date</th> </tr> </thead> <tbody> <tr> <td>SDA-001 V1</td> <td>Drug Administration</td> <td>03/02/2016</td> </tr> <tr> <td>T_CONMED V1</td> <td>Concomitant Medication Review</td> <td>03/02/2016</td> </tr> <tr> <td>AE-001 V1</td> <td>Adverse Event Assessment</td> <td>03/02/2016</td> </tr> <tr> <td>VITALS_Blood Pressure V1</td> <td>Vital Signs</td> <td>03/02/2016</td> </tr> <tr> <td>PE-001 V1</td> <td>Physical Examination</td> <td>03/02/2016</td> </tr> <tr> <td>T_CONMED V1</td> <td>Concomitant Medication Review</td> <td>03/02/2016</td> </tr> <tr> <td>QSTNR_QOL_BCTOS V1</td> <td>QOL Questionnaires</td> <td>04/30/2016</td> </tr> <tr> <td>CTMS_DA_ED003 V1</td> <td>CT or MRI, with contrast of brain</td> <td>04/30/2016</td> </tr> <tr> <td>VITALS_Blood Pressure V1</td> <td>Vital Signs</td> <td>04/30/2016</td> </tr> <tr> <td>PE-001 V1</td> <td>Physical Examination</td> <td>04/30/2016</td> </tr> </tbody> </table>						Form No.	Form Desc.	Visit Date	SDA-001 V1	Drug Administration	03/02/2016	T_CONMED V1	Concomitant Medication Review	03/02/2016	AE-001 V1	Adverse Event Assessment	03/02/2016	VITALS_Blood Pressure V1	Vital Signs	03/02/2016	PE-001 V1	Physical Examination	03/02/2016	T_CONMED V1	Concomitant Medication Review	03/02/2016	QSTNR_QOL_BCTOS V1	QOL Questionnaires	04/30/2016	CTMS_DA_ED003 V1	CT or MRI, with contrast of brain	04/30/2016	VITALS_Blood Pressure V1	Vital Signs	04/30/2016	PE-001 V1	Physical Examination	04/30/2016
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Subject Console
 Protocol No.: NEURO-EVANS-FEVERFEW
 MRN: 12345
 EPK:

In the **Subject Console**, the Forms by Status shows the forms for one subject.

Subject Status: OFF STUDY
 Sequence No.: 1

Switch Subject	Quarantined Forms	To Do Forms	Active Forms	Completed Forms	Planned Forms	Forms Summary																																																																																				
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Entering Data into a Form

Subject Console
To Do Forms

Navigate to the *Subject Console > Forms by Status > To Do Forms* (or the CRA Console if you want to look at all Subjects' To Do Forms)

Forms by Status
PE-001 V1
Click on the Physical Exam Form

Phase	Segment	Visit No.	Form Desc.	Visit Date
Treatment	Screening	MS-DA-ED003 V1	Evaluable Disease	03/02/2016
Treatment	Screening	T.CONMED V1	COPY FORWARD Concomitant Measures/Medications -	03/02/2016
Treatment	Screening	PE-001 V1	Physical Exam	03/02/2016
Treatment	Screening	QSTNR-QOL_BCTOS V1	Breast Cancer Treatment Outcomes Scale	03/02/2016
Treatment	Screening	VITALS_Blood Pressure V1	Resting BP and HR	03/02/2016
Treatment	Treatment	AE-001 V1	Adverse Events	04/30/2016
Treatment	Treatment	T.CONMED V1	COPY FORWARD Concomitant Measures/Medications -	04/30/2016
Treatment	Treatment	SDA-001 V1	Study Drug Admin	04/30/2016
Treatment	Treatment	PE-001 V1	Physical Exam	04/30/2016
Treatment	Treatment	QSTNR-QOL_BCTOS V1	Breast Cancer Treatment Outcomes Scale	04/30/2016
Treatment	Treatment	VITALS_Blood Pressure V1	Resting BP and HR	04/30/2016
Treatment	Treatment	AE-001 V1	Adverse Events	05/12/2016
Treatment	Treatment	T.CONMED V1	COPY FORWARD Concomitant Measures/Medications -	05/12/2016
Treatment	Treatment	SDA-001 V1	Study Drug Admin	05/12/2016
Treatment	Treatment	VITALS_Blood Pressure V1	Resting BP and HR	05/12/2016
Treatment	Treatment	AE-001 V1	Adverse Events	06/22/2016
Treatment	Treatment	T.CONMED V1	COPY FORWARD Concomitant Measures/Medications -	06/22/2016
Treatment	Treatment	SDA-001 V1	Study Drug Admin	06/22/2016

Subject Form Update

 Protocol No.: NEURO-EVANS-FEVERFEW
 Protocol Status: OPEN TO ACCRUAL

 MRN: 12345
 Subject Name: Peggy Moss

Subject Status: OFF STUDY

Sequence No.: 101

PE-001 V1
Save

The PE-001 v1 form opens. Enter the data and click Save

Category	Data Entry Begin Date	Visit Date (MM/DD/YYYY)	Missed	Not Applicable	Lab
PE-001 V1	09/06/2017	03/02/2016	N	N	

Body System	Finding	Comments
Abdomen	Not Examined	
Breasts		
Cardiovascular		

★ Subject Console
 Protocol Status: OPEN TO ACCRUAL Subject Status: OFF STUDY

MRN: 12345 Subject Name: Peggy Moss Sequence No.: 101

Switch Subject [Type here to search]

 Queried Forms To Do Forms **Active Forms** Completed Forms Planned Forms Forms Summary

Phase	Segment	Visit	Procedure	Form No.	Form Desc.	Visit Date	Data Entry Begin Date	Current Status	Delete?
Treatment	Screening	V1 (-8wks)	Physical Examination	PE-001.V1	Physical Exam	03/02/2016	09/06/2017	Started	

Submit Clear

The PE-001 v1 form now appears in the Active Forms tab. Anytime a "To Do" form is open it will move to the Active Forms tab.

Subject Form Update
 Protocol Status: OPEN TO ACCRUAL Subject Status: OFF STUDY

MRN: 12345 Subject Name: Peggy Moss Sequence No.: 101

Category	Data Entry Begin Date	Visit Date	Missed	Not Applicable	Lab	Phase	Visit	Status
PE-001 V1	09/06/2017	03/02/2016	N	N		Treatment	V1 (-8wks)	Started

Status History Change History

 Instructions View PDF **Complete**

Form 0 / 0 **Save**

Body System	Finding
Abdomen	Normal
Breasts	
Cardiovascular	

When all data entry for the form has been completed and qc checks performed, click Save and then Complete.

When a form is Complete, it moves into the Forms by Status > Completed Forms and is available for data export and/or monitoring

Grid Forms

Grid Forms are typically used for Concomitant Meds, Adverse Events and other data where there may be multiple rows of data collected at one visit.

This is a typical ConMed form. The data for one ConMed is entered in the upper portion.

Click Apply to save the data entered as a row.

First Dose Date	Last Dose Date	Medication	Total Daily Dose	Dose Unit	Schedule	Indication	Baseline Med
08/08/2017	09/07/2017	Propranolol	80	mg		Blood Pressure	No

No Records Found.

1 The Propranolol information is saved as a row

2 Enter the data for the next ConMed.

3 Click Apply

4 Continue adding the ConMeds, clicking Apply after every new entry. Click Save when you are done with the form. Click Complete when the form is final.

First Dose Date	Last Dose Date	Medication	Total Daily Dose	Dose Unit	Schedule	Indication	Baseline Med
08/08/2017	09/07/2017	Propranolol	80	mg	bid	Blood Pressure	No
08/18/2017		Pregabalin	10	mg	qd		