



Maximizing Clinical Trial Operations with Study Drugs: Coordinator Perspective

Jason Weimer, MA

Maximizing Clinical Trial Operations
for trials involving
Study Drugs and Investigational Products

**Increasing efficiency &
minimizing errors!**

Communication is Key!

- Early
- Clear
- Concise
- Correct
- Current study pharmacy MOP?



Components of a study drug order

- Patient
- Prescriber
- Drug
- Dosage/administration
- Payment
- Dispensing



Sample IDS order

- Highlight key info
- Double check for accuracy
- Send early even if not complete
- Use tools – DocuSign
- Per Institution

Subject Name: <u>SAMPLE PATIENT</u>
Subject ID: <u>1208</u>
Date/Time Due: <u>3/26/2024</u>
Deliver to: <u>CRC will pick-up</u>

PHYSICIAN'S ORDER SHEET
ASPIRE STUDY

AUTHORIZATION IS GIVEN TO PHARMACY TO DISPENSE AND TO THE NURSE TO ADMINISTER THE GENERIC OR CHEMICAL EQUIVALENT WHEN THE DRUG IS FILLED BY THE PHARMACY OF PRESBYTERIAN UNIV HOSPITAL OR MONTEFIORE UNIV HOSPITAL - UNLESS NAME IS CIRCLED

DATE	TIME	***IDS***STUDY20110249
2/26	1:00PM	<p>TITLE: Anticoagulation in Intracerebral Hemorrhage (ICH) Survivors for Stroke Prevention and Recovery (ASPIRE)</p> <p>IRB#: STUDY20110249</p> <p>PRINCIPAL INVESTIGATOR: <u>Marcelo Rocha, MD PhD</u></p> <p>CO-INVESTIGATORS: Matthew Starr, MD; Rebecca Pollard MD; Elissa Ortolani MD; Aaron Ravelo Jimenez, MD; Murat Sari, MD; Sarah Wondisford MD; Nirav Bhatt, MD; Ali Fadhil MD; Neil Suryadevara MD; Alhamza Al-Bayati, MD; Mohammad Kayyali MD; Mausaminben Hathidara, MD; Katharine Dermigny, MD; Victor Montalavan, MD; Sitara Koneru Achanti, MD; Yanal Shaheen, MD; Mohammad Ahmad, MD;</p> <p>COORDINATORS:</p> <p><u>Jason Weimer</u> Cell: 724-858-8722 Office: 412-647-5615</p> <p>Emma Gyurisin Cell: 412-584-8136 Office: 412-677-9128</p> <p>Denise McCarthy Cell: 412-225-4282 Office: 878-261-6015</p> <p>FAX ORDER TO (412)647-9651</p> <p>PATIENT CONSENT SIGNED: <u>YES</u> or NO (circle one) *****</p> <p>DISPENSE: ASPIRE STUDY DRUG KIT # <u>32613</u> (contains #100 aspirin 81mg/placebo tablets and #200 apixaban 2.5mg/placebo or 5mg/placebo tablets)</p> <p>DIRECTIONS: For aspirin 81mg/placebo tablets: Take ONE tablet by mouth ONCE daily.</p> <p>For apixaban 2.5mg/placebo or 5mg/placebo tablets: Take ONE tablet by mouth TWICE daily.</p> <p>PHYSICIAN PRINT NAME: <u>Marcelo Rocha, MD PhD</u></p> <p>PHYSICIAN SIGNATURE: _____ DATE: _____</p>

Sample IDS order

- Highlight key info
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- Use tools – DocuSign
- Per Institution

INVESTIGATIONAL DRUG SERVICE PATIENT ENROLLMENT SHEET

Study Title: Anticoagulation in Intracerebral Hemorrhage (ICH) Survivors for Stroke Prevention and Recovery (ASPIRE)

IRB#: STUDY20110249

PI: Marcelo Rocha MD, PhD

Patient Name: Sample A. Patient
first mi last

Patient Address: HOME ADDRESS
Pittsburgh, PA 15213

Patient Phone number: (412) 222-2222

Social Security Number or MRN: 123456789

Date of birth: 03/26/1934

Allergies: Fish, Milk, Lactose intolerance, Demerol, Demerol HCL, ibuprofen, Indocin, Tamofen, Vicodin

Patient signed informed consent on file: YES/ NO (circle one)

Scheduled first day of therapy: 03/26/2024

Enrollment completed by: Jason Weimer

Phone number for questions: 724-858-8722




Fax completed form to the IDS Office at 412-647-9651

Please call to IDS Office with any questions at 412-864-3270 (spectralink phone)


DOSE MODIFICATION			
Date	DRUG	MODIFICATION	REASON
1) _____	_____	_____	_____
2) _____	_____	_____	_____

Sample WebDCU f512

- Varies per trial
- Start early
- Get help
- Update as needed

View: **F512 Study Drug Kit Assignment**

Jason WEIMER Sign Out 

Help

[Edit CRF](#) | [View Audit Trail](#)

CRF ID:	F512 Study Drug Kit Assignment					Rule Status:	DCR:
13991							
Site:	1502 UPMC Presbyterian Hospital, Pittsburgh, PA	Subject:	1300	Visit:	Baseline	Submitted:	27-Jun-2023 13:18 Christy IRELAND
		Accept:		Verify:			25-Oct-2023 11:14 Adelekan ADEWUYI
No.	Item Description	Data Value					
	<i>Subject must be randomized before study drug kit can be assigned. If the study drug is permanently stopped, complete F514 first.</i>						
Q01	Subject is due for a drug kit	<input type="radio"/> No, study drug temporarily stopped <input checked="" type="radio"/> Yes <input type="radio"/> No, study drug permanently stopped					
Q22	Reason study drug temporarily stopped						
Q02b	Weight units	<input type="radio"/> kg <input checked="" type="radio"/> lb					
Q02a	Weight	246					
Q04b	If current weight is not available, enter the last known weight						
Q04b	Creatinine units	<input type="radio"/> µmol/L <input checked="" type="radio"/> mg/dL					
Q04a	Serum creatinine	1					
Q04a	If current Creatinine is not available, enter the last known Creatinine						
Q19	Date of creatinine blood draw	02-Jun-2023					
<i>Study drug dose level determination and drug kit ID assignment provided by WebDCU™</i>							
<i>No drug kit assigned if Creatinine is 2.5 mg/dL or higher. Adjusted dose kit (2.5 mg) if more than one Yes to questions Q02, Q03, and Q04. Regular dose kit (5 mg) if no more than one Yes to questions Q02, Q03, and Q04.</i>							
Q02ab	Weight (kg)	111.59					
	Derived from Q02a and Q02b						
Q03a	Age at this visit	69					
	Derived from Subject Enrollment Form Q10, Q11, and current visit date						
Q04ab	Serum creatinine (mg/dL)	1					
	Derived from Q04a and Q04b						
Q02	Weight is 60 kg or less	<input checked="" type="radio"/> No <input type="radio"/> Yes					
	Derived from Q02ab						
Q03	Age is 80 or older	<input checked="" type="radio"/> No <input type="radio"/> Yes					
	Derived from Q03a						
Q04	Serum creatinine is 1.5 or higher	<input checked="" type="radio"/> No <input type="radio"/> Yes					
	Derived from Q04ab						
Q20	Protocol required drug kit dose level	<input type="radio"/> No drug kit to be assigned <input type="radio"/> Adjusted dose (2.5 mg) <input checked="" type="radio"/> Regular dose (5 mg)					
	Derived from Q02, Q03, and Q04 by WebDCU						
Q05	Drug kit ID assigned	80107					
	Assigned by WebDCU						
Q06	Aspirin/aspirin placebo bottle ID assigned	133804					
	Assigned by WebDCU						
Q07	Apixaban/apixaban placebo bottle ID assigned	295864					
	Assigned by WebDCU						
<i>Second drug kit assignment (data entered by NDMC). If a second drug kit is required, contact NDMC.</i>							
Q09	Subject requires second drug kit	<input type="radio"/> No <input type="radio"/> Yes					
Q21	Second drug kit dose level	<input type="radio"/> Adjusted dose (2.5 mg) <input type="radio"/> Regular dose (5 mg)					
Q10	Second drug kit ID assigned						
Q11	Second drug kit aspirin/aspirin placebo bottle ID assigned						
Q12	Second drug kit apixaban/apixaban placebo bottle ID assigned						
Q13	Reason for second drug kit assignment						

3/26/24, 1:56 PM

WebDCU™ for ASPIRE Current User: Jason WEIMER



View: F513 Study Drug Kit Dispensing

Jason WEIMER Sign Out

Help

Edit CRF View Audit Trail

Sample WebDCU f513

- Varies per trial
- Drug assignment sheet signature required
- Check MOP
- Verification code

CRF ID:	21209	F513 Study Drug Kit Dispensing					Rule Status:	DCR:	
Site:	1502 UPMC Presbyterian Hospital, Pittsburgh, PA	Subject	1300	Visit	9 Month	Submit	19-Mar-2024 13:06 Jason WEIMER	Accept:	Verify:
No.	Item Description	Data Value							
<i>After the drug kit has been assigned and retrieved from the site's inventory, the drug kit ID and drug kit verification code must be entered prior to dispensing to the subject to confirm the correct kit was pulled. The date drug kit/bottles started should then be confirmed with the subject once received and started.</i>									
Q13	Subject ID	1300							
Q06	Subject started drug kit	<input type="radio"/> No <input checked="" type="radio"/> Yes							
Q14	Reason drug kit not started								
Q01	Drug kit ID started	86348							
Q02	Drug kit verification code	690							
The 3 digit verification code is located on the drug kit label.									
Q03	Date drug kit started	22-Mar-2024							
Date started should be the first date the subject started taking drug from this drug kit.									
Q04	Number of apixaban/apixaban placebo pills dispensed	200							
Derived by WebDCU.									
Q05	Number of aspirin/aspirin placebo pills dispensed	100							
Derived by WebDCU.									
<i>Second drug kit dispensing (information completed by NDMC). If a second drug kit is required, contact NDMC.</i>									
Q07	Second drug kit started	<input checked="" type="radio"/> No <input type="radio"/> Yes							
Q08	Second drug kit ID started								
Q09	Second drug kit verification code								
The 3 digit verification code is located on the drug kit label.									
Q10	Date second drug kit started								
Q11	Number of second apixaban/apixaban placebo pills started								
Q12	Number of second aspirin/aspirin placebo pills started								
GC	General comments	entered directly							

Last updated by Jason WEIMER on 19-Mar-2024 13:06

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Tips for study drug workflow

- Realistic patient / clinician expectations
- Helpers
- Cheat sheets for nursing