



LIFE CHANGING MEDICINE

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: SAMPLE PATIENT | | | |
|--|------------------|--|---|--|--|--|
| | | | Subject ID: <u>1208</u> | | | |
| | IAN'S ORDEI | | Date/Time Due: <u>3/26/2024</u> | | | |
| TO THE NURS EQUIVALENT OF PRESBYTE | SE TO ADMINISTER | HARMACY TO DISPENSE AND THE GENERIC OR CHEMICAL S FILLED BY THE PHARMACY AL OR MONTEFIORE UNIV CLED | Deliver to: <u>CRC will pick-up</u> | | | |
| DATE | тіме | ***IDS** | **STUDY20110249 | | | |
| 2/26 | TIME 1:00PM | and Recovery (ASPII IRB#: STUDY20110249 PRINCIPAL INVESTIGATOR: CO-INVESTIGATORS: Matthew SI Suryadevara MD; Alhamza Al-Ba Dermigny, MD; Victor Montalava MD; COORDINATORS: Jason Weimer Emma Gyurisin Denise McCarthy FAX ORDER TO (412)647-96 PATIENT CONSENT SIGNED DISPENSE: ASPIRE STUDY I (contains #100 aspirin 81mg/pla DIRECTIONS: | Marcelo Rocha, MD PhD tarr, MD; Rebecca Pollard MD; Eliss Ortolani MD; tarr, MD; Sarah Wondisford MD; Nirav Bhatt, MD; Ali Fadhil MD; Neil yati, MD; Mohammad Kayyali MD; Mausaminben Hathidara, MD; Katharine n, MD; Sitara Koneru Achanti, MD; Yanal Shaheen, MD; Mohammad Ahmad, Cell: 724-858-8722 Office: 412-647-5615 Cell: 412-584-8136 Office: 412-677-9128 Cell: 412-225-4282 Office: 878-261-6015 551 : TES or NO (circle one) | | | |
| | | For apixaban 2.5mg/placebo or 5mg/placebo tablets: Take ONE tablet by mouth TWICE daily. PHYSICIAN PRINT NAME: _ Marcelo Rocha, MD PhD | | | | |
| | | PHYSICIAN SIGNATURE: | DATE: | | | |
| | | | | | | |









Sample IDS order

- Highlight key info
- Double check for accuracy
- Send early even if not complete
- 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: | <u>Sample</u> first | <u>A.</u> mi | <u>Patient</u> last | |
|----------------------------|--|-----------------|------------------------|---------------------------------|
| Patient Address: | HOME ADDRESS Pittsburgh, PA 15213 | | | |
| Patient Phone num | ber: <u>(412) 222-2222</u> | | | |
| Social Security Nu | mber or MRN: <u>12345</u> | 6789 | | |
| Date of birth: <u>03/2</u> | 6/1934 | | | |
| | lk, Lactose intolerand | | emerol HC | L, ibuprofen, Indocin, Tamofen, |
| Patient signed info | rmed consent on file | : YES/NO | (circle one) | |
| Scheduled first day | of therapy: <u>03/26/</u> | 2024 | | |
| Enrollment comple | eted by: <u>Jason Weim</u> | ner | | |
| Phone number for | questions: <u>724-858</u> | -8722 | | |
| Please call to IDS C | m to the IDS Office a Iffice with any questi | ons at 412-86 | 4-3270 (spe | ectralink phone) |
| | | DOSE MOD | IFICATION | |
| Date 1) | DRUG N | | | REASON |
| 2) | | | | |





Sample WebDCU f512

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

| 6/24, 1:4 | 8 PM WebDCU™ for | ASPIRE Current User: Jason WEIMER |
|--------------|--|--|
| | EE12 CH | |
| | Subject View: F512 St | |
| WebDC | U ASPIRE CRF Assign | nment Holp |
| | | Edit CRF View Audit Trail |
| CRF ID: 1 | 3991 F512 Study Drug Kit A | ssignment Rule DCR: |
| | 502 UPMC Presbyterian Subject: 1300 Visit: Baseline Submit: 2 | 7-Jun-2023 13:18 Christy Accept: Verify: 25-Oct-2023 11:14 Adelekan |
| No. | Item Description | RELAND Venty ADEWUYI Data Value |
| no. | | ed. To receive a drug kit ID assignment, data enter and submit the CRF. If |
| Q01 | Subject is due for a drug kit | ○ No, study drug temporarily stopped t ○ Yes ○ No, study drug permanently stopped |
| Q22 | Reason study drug temporarily stopped | |
| Q02b | Weight units | |
| Q02a | Weight If current weight is not available, enter the last known weight | 246 |
| Q04b | Creatinine units | |
| | Serum creatinine | |
| Q04a | If current Creatinine is not available, enter the last known Creatinine | |
| Q19 | Date of creatinine blood draw | |
| | Study drug dose level determination and drug kit ID assignment | provided by WebDCU TM |
| | 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 G Regular dose kit (5 mg) if no more than one Yes to questions G | 102, Q03, and Q04. |
| | Weight (kg) | |
| Q02ab | Derived from Q02a and Q02b | 111.59 |
| | Age at this visit | |
| Q03a | Derived from Subject Enrollment Form Q10, Q11, and current visit date | 69 |
| | Serum creatinine (mg/dL) | |
| Q04ab | Derived from Q04a and Q04b | 1 |
| | Weight is 60 kg or less | |
| Q02 | | No ○Yes Yes |
| | Derived from Q02ab Age is 80 or older | |
| Q03 | | No ○Yes |
| | Derived from Q03a Serum creatinine is 1.5 or higher | |
| Q04 | | No ○Yes Yes |
| | Derived from Q04ab | |
| Q20 | Protocol required drug kit dose level | No drug kit to be assigned Adjusted dose (2.5 mg) |
| | Derived from Q02, Q03, and Q04 by WebDCU | Regular dose (5 mg) |
| Q05 | Drug kit ID assigned | 80107 |
| 205 | Assigned by WebDCU | |
| | Aspirin/aspirin placebo bottle ID assigned | |
| Q06 | Assigned by WebDCU | 133804 |
| | Apixaban/apixaban placebo bottle ID assigned | |
| Q07 | Assigned by WebDCU | 295864 |
| | Second drug kit assignment (data entered by NDMC). If a second | |
| Q09 | Subject requires second drug kit | |
| Q21 | Second drug kit dose level | |
| 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 | |







Sample WebDCU f513

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

3/26/24, 1:56 PM

ŧ/

ASPIR

WebDCU™ for ASPIRE Current User: Jason WEIMER

Jason WEIMER Sign Out

Help

| Subject CRF | View: | F513 | Study | Drug | Kit | Dispensing |
|----------------|-------|------|-------|------|-----|------------|
|----------------|-------|------|-------|------|-----|------------|

| D: 21209 FS13 Study Drug kit Dispensing Status: DCR 1502 UPMC Presbyterian Hospital, Pittsburgh, Subject 1300 Visit Month Submit 19-Mar-2024 13.06 Jason Accept: Verif Mo. Item Description Verif Verif Verif Verif Verif Verif After the drug kit has been assigned and retrieved from the site's inventory. The drug kit workscaton code must be entered with the subject once received and started. Verif Verif Q06 Subject 1D 1300 Image: Status Verif Q14 Reason drug kit Data drug kit workscaton code must be entered drug kit No Verif Q07 Drug kit Data drug kit Status Status Status Q08 Subject 1D 1300 Status Status Q09 Drug kit verification code is located on the drug kit atarted drug kit Status Status Q01 Drug kit Data drug kit atarted Status Status Status Q02 The 3 digit verification code is located on the drug kit tatarted drug kit Status Status Q03 Date started should be the first date the subject started taking drug kit atarted Status Status Q04 Number of apixaban/apixaban placebo pills dispensed Derived by WebDCU. Image: S | | | | | | | | Edit CRF | /iew Audit Tra |
|---|------------|--|---------------------|--------------------------------|---------------|--------------|-------------|----------|----------------|
| PA Item Description Subject J00 Visit Month Submit WEIMER Pacept Vent No. Item Description Data Value Data Value value Value Data Value Data | CRF ID: | 21209 | | F513 Study Drug Kit Dispensing | | | | DCR: | |
| 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 to confirm the singlect to the subject to confirm the singlect to confirme | Site: | 1502 UPMC Presbyterian Hospital, Pittsburgh, PA | Subject 1300 Vis | it: ⁹ Month | | | 13:06 Jason | Accept: | Verify: |
| 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. Q13 Subject ID Q06 Subject started drug kit Q11 Reason drug kit no started Q01 Drug kit perfication code Q02 Drug kit verification code is located on the drug kit tateted Q03 Date started should be the first date the subject started taking drug from this drug kit Q04 Number of apixaban/apixaban placebo pills dispensed Q05 Second drug kit started Q06 Second drug kit started Q07 Second drug kit started Q08 Second drug kit started Q09 Second drug kit started Q10 Date second drug kit started Q11 Number of second apytin/aspirin placebo pills dispensed Q11 Second drug kit started Q12 Number of second apytin/aspinin placebo pills started <th>No.</th> <th>Item Description</th> <th></th> <th></th> <th></th> <th></th> <th>Data Value</th> <th></th> <th></th> | No. | Item Description | | | | | Data Value | | |
| Q06 Subject started drug kit Reason drug kit not started No Yes Q14 Reason drug kit not started | | prior to dispensing to the subject to confirm the correct kit was pulled. The date drug kit/bottles started should then be confirmed with th | | | | | | | |
| 014 Reason drug kit not started 001 Drug kit Di started 002 Drug kit Di started 003 Drug kit verification code is located on the drug kit label. 004 Date started should be the first date the subject started taking 005 Date started should be the first date the subject started taking 006 Number of apixaban/apixaban placebo pills dispensed 007 Derived by WebDCU. 008 Second drug kit dispensing (information completed by NDMC). It a second drug kit is required, contact NDMC. 007 Second drug kit blastered 008 Second drug kit verification code is located on the drug kit label. 009 Second drug kit started 009 The 3 digit verification code is located on the drug kit label. 010 Date second drug kit started 0201 Number of second apixaban/apixaban placebo pills started 0202 Second drug kit started 0203 Second drug kit started 0204 Number of second apixaban/apixaban placebo pills started 0205 Second drug kit started 0206 Second drug kit started 0207 Second drug kit started 0208 Second drug kit started 0209 Second drug kit started 0210 Date second drug kit started | Q13 | | Subject ID | 1300 | | | | | |
| Q01 Drug kit ID started 86348 Q02 Drug kit verification code 660 The 3 digit verification code is located on the drug kit started 660 Q03 Date started should be the first date the subject started taking drug from this drug kit. 22-Mar-2024 Q04 Number of apixaban/apixaban placebo pills dispensed 200 Q05 Number of apirin/aspirin placebo pills dispensed 200 Q06 Number of apirin/aspirin placebo pills dispensed 100 Q07 Second drug kit started MO Q08 Second drug kit started MO Q09 Second drug kit started MO Q09 Second drug kit started MO Q10 Date second drug kit started IN Q11 Number of second apixaban/apixaban placebo pills started Intervel by VebDCU. | Q06 | Subject | ct started drug kit | No | Yes | | | | |
| Q02 Drug kit verification code 690 The 3 digit verification code is located on the drug kit label. 090 Q03 Date started should be the first date the subject started taking drug from this drug kit. 22-Mar-2024 Q04 Number of apixaban/apixaban placebo pills dispensed 200 Q05 Number of aspirin/aspirin placebo pills dispensed 200 Q06 Number of aspirin/aspirin placebo pills dispensed 100 Second drug kit dispensing (information completed by NDMC). If a second drug kit is tarted No Yes Q08 Second drug kit started No Yes Q09 Second drug kit started No Yes Q01 Date second drug kit started No Yes Q03 Second drug kit started QNO Yes Q04 Derived by NDMC). If a second drug kit is tarted QNO Yes Q03 Second drug kit started QNO Yes Q04 Second drug kit started QNO Yes Q05 Second drug kit started QNO Yes Q04 Date second drug kit started | Q14 | Reason dr | ug kit not started | | | | | | |
| QQ2 E80 The 3 digit verification code is located on the drug kit label. E80 QQ3 Date started should be the first date the subject started taking drug first indrug kit. 22-Mar-2024 QQ4 Number of apixaban/apixaban placebo pills dispensed 200 QQ4 Derived by WebDCU. 200 QQ5 Number of aspirin/aspirin placebo pills dispensed 200 QQ6 Derived by WebDCU. 100 Second drug kit dispensing (information completed by NDMC). If a second drug kit is required, contact NDMC. 200 QQ7 Second drug kit blastered 0N @Yes QQ8 Second drug kit label. No @Yes QQ9 Second drug kit label. Pate second drug kit label. Q10 Date second drug kit started 21 Q11 Number of second aspirin/aspirin placebo pills started 21 | Q01 | D | rug kit ID started | 86348 | | | | | |
| Q03 Date started should be the first date the subject started taking drug from this drug kit. 22-Mar-2024 Q04 Number of apixaban/apixaban placebo pills dispensed 200 Q05 Derived by WebDCU. 200 Second drug kit dispensing (information completed by NDMC). If a second drug kit is required, contact NDMC. 100 Q08 Second drug kit started No Q09 Second drug kit started No Q10 Date second drug kit started No Q11 Number of second apixitaspiring placebo pills started | Q02 | 5 | | 690 | | | | | |
| Q04 Derived by WebDCU. 200 Q05 Number of aspirin/aspirin placebo pills dispensed Derived by WebDCU. 100 Second drug kit dispensing (information completed by NDMC). If a second drug kit is required, contact NDMC. Q07 Q07 Second drug kit started No Q08 Second drug kit started No Q09 Second drug kit started No Q10 Date second drug kit label. Q11 Number of second apixabar/apixaban placebo pills started Q12 Number of second aspirin/aspirin placebo pills started | Q03 | Date started should be the first date the subject started taking | | | 024 | | | | |
| QQ05 Derived by WebDCU. 100 Second drug kit dispensing (information completed by NDMC). If a second drug kit is required, contact NDMC. QQ07 QQ07 Second drug kit started No Yes QQ08 Second drug kit lo started QQ09 Second drug kit lo started QQ09 Second drug kit started Q10 Date second drug kit started Q11 Number of second aspirinkaspirin placebo pills started Q12 Number of second aspirinkaspirin placebo pills started | Q04 | 200 | | | | | | | |
| Q07 Second drug kit started No Yes Q08 Second drug kit ID started Q09 Second drug kit Verification code Q09 The 3 digit verification code is located on the drug kit started Q10 Date second drug kit started Q11 Number of second apixaban/apixin/aspirin/placebo pills started Q12 Number of second aspirin/aspirin placebo pills started | Q05 | | | 100 | | | | | |
| O08 Second drug kit ID started Op9 Second drug kit verification code Op9 The 3 digit verification code is located on the drug kit label. O10 Date second drug kit started O211 Number of second apixaban/placebo plils started O212 Number of second aspirin/aspirin placebo pills started | | Second drug kit dispensing (information complet | ed by NDMC). If | a second | drug kit is i | equired, con | tact NDMC. | | |
| Second drug kit verification code Q09 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 apirinkapirin placebo pills started | Q07 | Secon | d drug kit started | No | Yes | | | | |
| Q09 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 | Q08 | | | | | | | | |
| Q11 Number of second apixaban/apixaban placebo pills started Q12 Number of second aspirin/aspirin placebo pills started | Q09 | • | | | | | | | |
| Q11 Number of second apixaban/apixaban placebo pills started Q12 Number of second aspirin/aspirin placebo pills started | Q10 | Date secon | d drug kit started | | | | | | |
| Q12 Number of second aspirin/aspirin placebo pills started | Q11 | | <u> </u> | | | | | | |
| | Q12 | | | | | | | | |
| | | | | entered | lirectly | | | | |

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

