PHARMAROUND
INTERAKTIVNÍ PLATFORMA

Investigator site file

ŠKOLA KLINICKÝCH HODNOCENÍ V PRAXI
2. – 4. duben 2014, Hotel Medlov

Tento projekt je spolufinancován Evropským sociálním fondem a státním rozpočtem České republiky.

esf evropský sociální fond v ČR
EVROPSKÁ UNIE
MINISTERSTVO ŠKOLSTVÍ, MLÁDEŽE A TĚLOVÝCHOVY
OP Vzdělávání pro konkurenceschopnost
UNIVERSITAS MASARYKIANA BRUNENSIS

INVESTICE DO ROZVOJE VZDĚLÁVÁNÍ

Investigator site file

1. Contact Details & Site Visit Log

1.1Quintiles/Sponsor/Third Party Contact List

1.2 Site Visit Log

2. Study Communications

2.1 Correspondence with Quintiles

2.2 Correspondence with Sponsor

2.3 Correspondence with third Parties

2.4 Telephone contacts

3. Subject information

3.1 Subject Pre-Identification Log

3.2 Subject Screening / Enrollment Log

3.3 Immediately Reportable Adverse Event (IRAE) log & IRAE Reports File SAE reports (or equivalent) per subject, per event (including Initial and Follow-up reports).

3.4 Blank patient ID card

Investigator site file

4. Protocol and Amendments

4.1 Current version of Protocol /Amendment
4.2 Protocol / Amendment Signature Page(s)
4.3 Protocol /Amendment Receipt Page(s)
4.4 Superseded versions of Protocol / Amendments

5. Safety Information

5.1 Investigator's Brochures (all versions)
5.2 IDB Receipt page
5.3 Safety Reports

6. Regulatory

6.1 Application and approvals
6.2 Site Specific Regulatory Documentation/ Correspondence
6.3 Progress Reports
6.4 Local or Country Specific Required Documentation

7. IEC / IRB

7.1 Submissions, opinions and approvals – central and local as applicable
7.2 Composition

Investigator site file

7.3 Blank set of informed consent forms and subject information sheets - File all approved versions applicable to this site. File translations if applicable

Main study ICF

Optional pharmacogenetic/biomarker ICF

7.4 Subject advertisement and appropriate approvals

7.5 Other patient tools submitted to EC/IRB:

Patient Referral Leaflet

Poster

Thank You Postcard

Dr to Patient Letter

Patient Study Guide

7.6 Patient questionnaires

Health Assessment Questionnaire Disability Index (HAQ-DI)

Patient Global Assessment of Disease Activity VAS

Patient Pain VAS – included in HAQ-DI

Short Form 36 (SF-36) questionnaire

8. Investigator Agreement

8.1 Confidential Disclosure Agreement

8.2 Clinical Trial Agreement / Financial contract

8.3 Indemnification / Insurance certificate/ documentation

8.4 Other Investigator Agreement - File all completed updates of the FDA 1572 (US only). File Health Canada: Qualified Investigator Undertaking Form (if applicable)

8.5 Financial disclosure forms & EU Consents (if applicable)

8.6 Site 21 CFR Part 11 Information - File the Part 11 Site Representation Form. File copy of site's eSignature letter to FDA

Investigator site file

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9. Site Staff Details

9.1 Study Personnel Signature/ Delegation Form

9.2 CV of Principal Investigator

9.3 CV of sub-investigator (s)

9.4 CV of other relevant study staff

9.5 Other relevant documents as applicable –

Signed Blinding Plan

Investigator Prescription Form

Investigator site file

10. Investigational Product

10.1 IP accountability records
Shipping records,
Acknowledgement of receipt,
Dispensing logs/ Drug Accountability Records,
Return or destruction forms
10.2 Unblinded/Placebo Accountability Records
Shipping records,
Acknowledgement of receipt,
Dispensing logs/ Drug Accountability Records,
Return or destruction forms.
Docs kept in the Unblinded Pharmacy File during the treatment phase until COV (Section 7).
Docs inserted in this section at the end of the study, at the time of Filing reconciliation.
10.3 Certificate of analysis – if available and applicable.
Per ICH/GCP it is not required to file a CoA at the investigator's site
10.4 IP storage records (temperature logs)
10.5 storage records (temperature logs)
Docs kept in the Unblinded Pharmacy File during the treatment phase until COV (Section 7).
Docs inserted in this section at the end of the study at the time of Filing reconciliation.
10.6 Randomization codes / unblinding envelopes – Not applicable, managed by IVRS
10.7 Instructions for handling of IP
10.8 IVRS Manual
10.9 IVRS worksheets
10.10 Blinded worksheet (pharmacist worksheet)
10.10 IVRS notifications
10.11 IVRS Unblinded notifications.
Docs kept in the Unblinded Pharmacy File during the treatment phase until COV (Section 7).
Docs inserted in this section at the end of the study, at the time of Filing reconciliation.

Investigator site file

1**1. Case Report Form**

11.1 Completed CRFs & Queries – to be provided electronically at end of study
11.2 Blank copy of CRF

12. Laboratory

12.1 Laboratory certificates / accreditation
12.2 Reference ranges
12.3 Lab Correspondence
12.4 CV of laboratory head
12.5 Record of retained samples – Also file laboratory Requisition Forms
12.6 Laboratory sample storage records
File freezer temperature log
File confirmation of receipt for samples received
12.7 Laboratory manual
12.8 Contract with Laboratory (local only as applicable)

13. Other Study Specific Documents

13.1 Confirmation list / Certificate(s) of investigator meeting attendance
13.2 Investigators Meeting Documentation
13.3 Study Instruction Materials / User manuals
PHT ePRO Device Manual
13.4 Pre- trial Documentation – completed SIF
13.5 Initiation Visit Documentation – copy of initiation visit report
13.6 Additional Site Staff Training
13.7 Audit Certificate

Investigator site file

14. Study Results / Reports

14.1 Clinical Study Report

15. Confidential Site Documents

15.1 Subject Identification List

15.2 Signed copies of Informed Consents and Subject Information Sheets

15.3 Source documents

16. Site Financial Documentation

16.1 Subject Reimbursements

16.2 Other Site Specific Finances

17. Site Tools

17.1 Study material accountability records

Blood pressure monitor

Thermometers as applicable

Other items as applicable

17.2 Access to Patients Investigator Tool examples (as applicable per site) – patient facing example to be filed in section 7.5 with relevant EC approvals.