



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.



evropský  
sociální  
fond v ČR



EVROPSKÁ UNIE



MINISTERSTVO ŠKOLSTVÍ,  
MLÁDEŽE A TĚLOVÝCHOVY



INVESTICE DO ROZVOJE VZDĚLÁVÁNÍ

# Investigator site file

## **1. Contact Details & Site Visit Log**

- 1.1 Quintiles/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- 4.4 Superseded versions of Protocol / Amendments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**

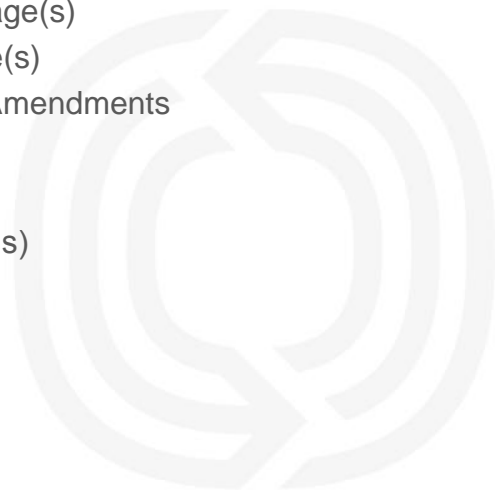
- 5.1 Investigator's Brochures (all versions)
- 5.2 IDB Receipt page
- 5.3 Safety Reports

## **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

## **8. Investigator Agreement**

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

## **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

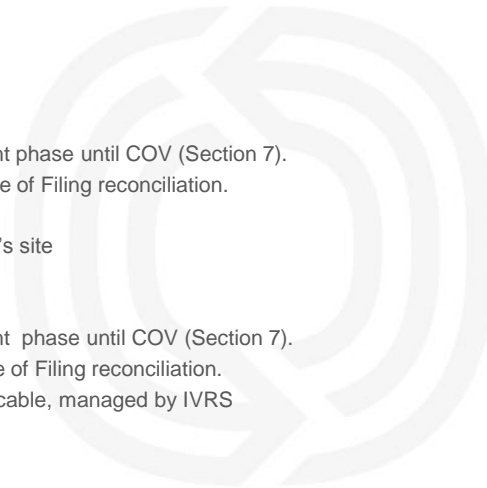
### 10.10 Blinded worksheet (pharmacist worksheet)

### 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.



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## **11. 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

# 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.

