Essential Documents
What are Essential Documents?

- “Essential documents are those documents which individually and collectively permit evaluation of the conduct of the trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor and monitor with the standards of Good Clinical Practice and with all applicable regulatory requirements” (ICH Guideline E6).
Signed Protocol and Amendments – to document investigator and sponsor agreement to the protocol and any amendments

- Current protocol and all previously approved versions
- When applicable, a copy of the fully executed protocol signature page for original protocol and all approved versions
Protocol Signature Page

<table>
<thead>
<tr>
<th>Boehringer Ingelheim</th>
<th>24 Oct 2013</th>
</tr>
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<tbody>
<tr>
<td>BI Trial No.: 1218.22</td>
<td>Page 1 of 1</td>
</tr>
<tr>
<td>Doc. No.: U13-1186-02</td>
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**LOCAL SIGNATURES**

(Principal Investigator of site AND Local Clinical Monitor (CML))

**Trial Title:** A multicenter, international, randomized, parallel group, double-blind, placebo controlled CArdiovascular Safety & Renal Microvascular outcome study with LINAgliptin, 5 mg once daily in patients with type 2 diabetes mellitus at high vascular risk. CARMELINA

**Trial Number:** 1218.22

**Protocol Version:** 2.0

Local Clinical Monitor:

30.10.2013

Drs. Ing. David Baanstra, MBA
Boehringer Ingelheim bv
Medical department
Comeniusstraat 6
1817 MS Alkmaar
The Netherlands

I herewith certify that I agree to adhere to the trial protocol and to all documents referenced in the trial protocol.

**Principal Investigator (site):**

08/13/2015

Signed signature page is located in the electronic Clinical Trial Master File
Investigator Brochure (if applicable) - To document that relevant and current scientific information about the investigational product has been provided to the investigator.

- **Current IB and all previously approved versions**
- **When applicable, a copy of the IB signature page for original protocol and all approved versions**
Essential Documents

CVs and Licensure – to document qualifications and eligibility to conduct trial and/or supervise medical supervision of subjects

- Signed and dated CVs for all study staff
- Valid medical licenses/professional certifications for all study staff
Medical License

Medicine Board of California

Make sure it not expired...
FDA Form 1572—Statement of Investigator, documents the PI agreement to accept responsibility for the study, specifically to:

1) Follow the protocol,
2) Personally conduct or supervise the trial,
3) Obtain IRB approval and informed consent of subjects,
4) Report any adverse events,
5) Have read the IB and understand the risks and side effects,
6) To ensure that everyone working on the study is informed and trained on the above items,
7) To maintain accurate records and to make the records available for inspection,
8) To ensure that IRB approval is maintained, all unanticipated problems are reported to the IRB and that no changes will be made without IRB approval (except for immediate safety concerns).

- An FDA-1572 is required for drug or biologic studies conducted under an IND, whether in the U.S. or abroad.
**Essential Documents**

**IRB Approvals** – to document that the trial has been subject to IRB review and has been given approval. As well as to identify the version date of the documents.

- Approval letters and/or notification of IRB decisions.
- Investigator response(s) to IRB notification (if applicable).
- Approved recruitment materials.
- Approved educational materials/additional study information distributed to subjects (e.g., subject diary).
- Memo regarding FWA, IRB registration. Copy of IRB membership roster.
UNIVERSITY OF CALIFORNIA, DAVIS
OFFICE OF RESEARCH
IRB Administration

June 23, 2015
Ranith Hagerman, MD
Dear Dr. Hagerman:

On June 22, 2015 the IRB reviewed the following protocol:

Type of Review: Initial
Title: A Double Blind Randomized Placebo Controlled Study of CM-AT for the Treatment of Autism in Children With All Levels of Fecal Chimerism
Investigator: Ranith Hagerman, MD
IRB ID: 770665-1
Funding: Curamark LLC
Grant ID: None
IND, IDE or HDE: 73,039
Documents Reviewed: Application, Consent Form, Parent Diary, Investigator Brochure, Surveys, Description of Study, Sponsor Protocol

The IRB approved the protocol from June 22, 2015 to June 21, 2016 inclusive.

Risk Determination: Greater than Minimal Risk
Comments/Conditions: Treatment Group – Minors Risk 0.2
Placebo Group – Minors Risk 0.2
Permission is to be obtained from the parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

As indicated in Section 46.107(c) of Title 45 of the Code of Federal Regulations and per the practice of this Institutional Review Board (IRB), no IRB member will participate in the IRB’s initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. No IRB member with a conflicting interest was present for the deliberation and vote for the above protocol.

This Assurance, on file with the Department of Health and Human Services, covers this activity:
FWA No: 00004557
Expiration Date: April 14, 2020
IORG: 0000251

Page 1 of 2

Page 2 of 2
Essential Documents

**IRB Approved Consent Form** – to document that the Informed Consent Form has been subject to IRB review and has been given approval. As well as to identify the version date of the documents.

- **Current IRB-approved consent and/or assent form version(s) with the IRB approval stamp.**
Permission to Take Part in a Human Research Study

Title of research study: A Double Blind Randomized Placebo Controlled Study of CM-AT for the Treatment of Autism in Children with All Levels of Fecal Chymotrypsin.

Investigator: Dr. Randi Hagerman

Why am I being invited to take part in a research study?
We invite your child to take part in this research study because he/she has been diagnosed with autism.

What should I know about a research study?
(Experimental Subject’s Bill of Rights)
• Someone will explain this research study to you, including:
  o The nature and purpose of the research study.
  o The procedures to be followed.
  o Any drug or device to be used.
  o Any common or important discomforts and risks.
  o Any benefits you might expect.
  o Medical treatment, if any, that is available for complications.
  o Whether or not you take part is up to you.
• You can choose without force, fraud, deceit, duress, coercion, or undue influence.
• You can choose not to take part.
• You can agree to take part now and later change your mind.
• Whatever you decide, it will not be held against you.
• You can ask all the questions you want before you decide.
• If you agree to take part, you will be given a signed and dated copy of this document.

Who can I talk to?
If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 916-703-0331.

For non-emergency issues you can call the UCDMC Hospital Operator (916-734-2011), tell the Operator you are participating in a research study and you wish to talk to Dr. Hagerman. In the case of an emergency, dial 911 from any phone.

This research has been reviewed and approved by an Institutional Review Board (“IRB”). Information to help you understand research is on-line at http://www.research.ucdavis.edu/policiescompliance/irb-admin. You may talk to an IRB staff member at (916) 703-9151, IRBAdmin@ucdmc.ucdavis.edu, or 2921 Stockton Blvd, Suite 1400, Room 1429, Sacramento, CA 95817 for any of the following:

For IRB Use

APPROVED by the Institutional Review Board
at the University of California, Davis

Protocol

Document Revision Date: January 24, 2013

770055
05-28-2013

ICF Version Date: 06.22.2016
Essential Documents

Logs – Staff

- Delegation of Authority/Delegation of Responsibility Log: documents the study-related procedures delegated to staff. The PI should initial, sign and date this list, and update it as new staff or study procedures are added to the protocol.

- Training Log: documents training of all study staff on protocol-related procedures.
Delegation of Responsibilities Log

Investigator Name: | Protocol: | Site Number:

List staff to whom the Principal Investigator (PI) has delegated significant study-related duties.

<table>
<thead>
<tr>
<th>Name</th>
<th>Responsibilities*</th>
<th>Initials</th>
<th>Signature</th>
<th>Start Date</th>
<th>End Date</th>
<th>PI Initials/Date</th>
</tr>
</thead>
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By initialing above, I, the PI, declare that during the conduct of the above study, I have delegated the following study-related activities:

*Responsibilities Legend

1. Administer consent
2. Screen subjects
3. Obtain medical history
4. Perform physical exam
5. Determine eligibility
6. Randomize subjects
7. Dispense study drug
8. Drug accountability
9. Assess adverse events
10. Complete source documents
11. Complete study forms
12. Provide discharge instructions
13. Make follow-up phone calls
14. Query management
15. 

Signature of Principal Investigator: ___________________________ Date: ___________________________
Logs – Subjects

- Pre-Screening Log: Captures subjects who have been pre-screened to determine initial eligibility for enrollment.
- Enrollment Log: Captures all subjects who sign a consent form.
- Adverse Event Tracking Log: Tracks and ensures timely reporting of all applicable adverse events to the IRB. This is often done electronically.
- Minor Deviation/Violation Tracking Log: Provides a record of all minor deviations from the approved protocol and facilitates reporting at continuing review. This is often done electronically.
- Tissues and/or Blood Sample Log: Tracks tissue and/or blood samples collected during research.
### Screening Log

<table>
<thead>
<tr>
<th>Subject screening #</th>
<th>Date Screened</th>
<th>Eligible? (Yes/No)</th>
<th>Date of Consent</th>
<th>Subject # and/or Randomization # Assigned (If applicable)</th>
<th>Reason for Exclusion/Screen Failure</th>
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* It is recommended that you use a non-identifying or random number to identify subjects at pre-screening (no initials). A key to re-identify should not be shared unless approved by the IRB and/or a HIPAA waiver of authorization is obtained.
# Adverse Event Log

**Protocol:** (Insert title or protocol number here)  
**Subject ID:** ____________________

<table>
<thead>
<tr>
<th>Adverse Event:</th>
<th>Adverse Event:</th>
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<tbody>
<tr>
<td>Serious Criteria Met?</td>
<td>Yes ☐ No ☐</td>
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<tr>
<td>Onset Date:</td>
<td>Onset Date:</td>
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<td>Onset Time (24hr clock):</td>
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<td>Severity:</td>
<td>Severity:</td>
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<td>□ Mild</td>
<td>□ Mild</td>
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<td>□ Moderate</td>
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<td>□ Severe</td>
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<td>IP Dose Action Taken:</td>
<td>IP Dose Action Taken:</td>
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<td>□ None</td>
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<td>□ Increased</td>
<td>□ Increased</td>
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<td>□ Reduced</td>
<td>□ Reduced</td>
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<td>Concomitant Medication Action Taken:</td>
<td>Concomitant Medication Action Taken:</td>
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<td>□ None</td>
<td>□ None</td>
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<td>□ Increased</td>
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<td>□ Reduced</td>
<td>□ Reduced</td>
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<td>Subject Action Taken:</td>
<td>Subject Action Taken:</td>
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<td>□ Withdrawn</td>
<td>□ Withdrawn</td>
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<td>□ Other, Specify:</td>
<td>□ Other, Specify:</td>
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<td>□ Treatment Given</td>
<td>□ Treatment Given</td>
</tr>
<tr>
<td>□ None</td>
<td>□ None</td>
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</table>

**Causality:**  
Related to study treatment:  
□ Yes/Unknown ☐ No  
If No, what was the most likely cause:  
□ Disease under study  
□ Background study drug: Specify ______________________  
□ Concomitant treatment: Specify ______________________  
□ Other: Specify ______________________  
□ Injection/procedure related: ☐

**Institution Signature & Date:** ______________________

**Is the AE ongoing at the end of the study?**  
□ Yes ☐ No
<table>
<thead>
<tr>
<th>If No, Stop date:</th>
<th>Comments:</th>
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**UC DAVIS CLINICAL AND TRANSLATIONAL SCIENCE CENTER**
### Subject Visit Tracking Log

<table>
<thead>
<tr>
<th>Subject ID</th>
<th>Consent Date</th>
<th>Baseline</th>
<th>Week 1</th>
<th>Week 2</th>
<th>Week 4</th>
<th>Final Status</th>
<th>Comments</th>
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Lab Documents – to document normal values and/or ranges of tests as well as to document qualifications of lab.

- Current Lab Certification (e.g., CLIA, CAP).
- Normal Lab/Reference Values.

Available at: [https://www.testmenu.com/ucdavis](https://www.testmenu.com/ucdavis)
Essential Documents

**Drug/Device Accountability** – to document that investigational product has been maintained and used according to protocol.

- Drug/Device shipment and receipt records.
- Drug/Device Accountability Log.
<table>
<thead>
<tr>
<th>Subject ID# and/or initials</th>
<th>Lot or Kit Number</th>
<th># Bottles, Vials, etc.</th>
<th>Amount of Study Drug per Bottle, Vial, etc.</th>
<th>Total Amount Dispensed</th>
<th>Initials</th>
<th>Date Dispensed</th>
<th>Date Returned</th>
<th># of Bottles, Vials, etc. Returned</th>
<th>Total Amount Returned</th>
<th>Balance: Number Dispensed Less Number Returned</th>
<th>Comments: Subject lost, discarded</th>
<th>Initials</th>
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Essential Documents

Data Collection – to document all data that is being captured for the study.

- Blank set of CRFs, data collection sheets, and IRB-approved study questionnaires.
- If data are being captured electronically a copy of the eCRF completion guidelines could be filed here.
Essential Documents

Correspondence— to document any agreements or significant discussions regarding trial administration, protocol violations, trial conduct or adverse event reporting.

- All relevant communications, other than site visits, to document any agreement or significant discussions regarding trial or administration, protocol violations, trial conduct, adverse event reporting, etc.
- Includes communications to and from the Sponsor and/or the study team.

Note: Communications about a specific subject should be filed with source documents for that subject.
Monitoring – to document site visits by, and findings of, the monitor.

- Monitoring Log: Documents any form of study oversight/monitoring. Both the monitor and clinical research coordinator should sign the log.
- Pre-study Visit Report, Site Initiation Visit Reports, Monitoring Visit Reports, Close-Out visit reports or follow up letters if visit reports are not provided.
Subject Identification Code List – to document a confidential list of names of all subjects and their associated unique identifiers. Allows PI to reveal identity of subjects if necessary.

- This is a document containing a unique identifier assigned by the investigator to each trial subject to protect the subject's identity and used in lieu of the subject's name when the investigator reports adverse events and/or other trial related data.
- This document allows for decoding in the event of an emergency.
Subject Code List

<table>
<thead>
<tr>
<th>Subject Name</th>
<th>Subject Initials</th>
<th>Subject # and/or Randomization # Assigned</th>
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<tbody>
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Essential Documents

Final Study Report – to document completion of trial.

- Final report by the Investigator to the IRB, and where applicable, to the regulatory authorities to document completion of the trial.
Source Documents
What is source documentation?

**ICH E6 1.52 source documents**

Original documents, data and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects’ diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, X-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial).
What is source documentation?

A source document is first instance a data point is recorded.

**Thus it is highly recommended that you create your own data collection tool.**
What is source documentation?

The most important purpose of source documentation in a clinical trial is to reconstruct the trial as it happened.

- It should enable an independent observer to reconfirm the data.
- Documentation should be such that it is able to provide audit trail to permit investigation if and when required.
Source Documentation

Study Visit # __

DATE OF VISIT: ___/___/___

VITAL SIGNS
Oral Temperature _______ C  Respiration Rate _________ minute
Pulse Rate _________/minute  Weight _______ Kgs  Pressure _________ mmHg

DIARY CARD RETRIEVED  Reviewed with Subject

CONCOMITANT THERAPY
Review and revise Concomitants Therapy Log for medications
☐ No Changes  ☐ Change

ADVERSE EVENTS (Review previous entries on Adverse Events Tracking Log)
☐ New AEs or health changes noted on the Adverse Event Tracking Log and progress note
☐ No new AEs or health changes reported
☐ Previous AE(s) evaluated and current status recorded

STUDY MEDICATION
Kit # Dispensed: _________
Drug return: ☐ Yes  ☐ No  Number of tablets returned: _________

DIARY CARD  ☐ Dispensed & Instruction's Reviewed
Next appointment scheduled ____________________ (___-___ day window, extension requires Sponsor's approval)

Comments:

This is a form used for recording details of a medical visit, including vital signs, medication, and adverse event notes. It is part of a clinical trial protocol.
What is good source documentation?

A – Attributable
L - Legible
C - Contemporaneous
O – Original
A – Accurate
Definitions

- A-Who created record
- L-Readable
- C-Timely
- O-First time written
- A-Correct, “whole truth”
Study Execution and ALCOA

- Informed Consent
- Source Docs
- Notes to file and other documentation
Informed Consent

11/11/05 ICF was signed by the subject.

☑ Attributable
☑ Legible
☑ Contemporaneous
☑ Original
☑ Accurate
Informed Consent

After talking to the subject on the phone, the subject agreed to come in to clinic with wife. ICF was reviewed, pt was given adequate time to assess participation in trial with wife. After all questions and concerns were resolved, pt signed consent form.

- Attributable
- Legible
- Contemporaneous
- Original
- Accurate
Corrections

- Scribble over mistake
- Back date note
- White out mistake
- Write over mistake
Informed Consent

Check all that apply:

- The subject meets all eligibility requirements.
- Discussed, explained and reviewed the consent form with subject.
  - Verbal consent was obtained (per IRB approved consent process)
  - Surrogate consent was obtained (per IRB approved consent process)
- All of the subject’s questions were answered/concerns addressed. (document multiple subject contacts below)
  - Subject did not have any questions/concerns
- Subject was given time to review the consent form and to discuss participation in this study with family members/others.
- The subject has agreed to participate in the study and signed/dated a valid consent form prior to the start of any study procedures.
- The consent process was witnessed by a third party (if applicable).
  - Witnessed by:
- A copy of the signed and dated consent form was given to the subject.
- A copy of the signed and dated consent form was placed in the medical record.
- A copy of the signed and dated consent form was placed in the research record.

Signature/initiars: C.J. [Signature]

Date: 11 Nov 2013

Date | Time | Comments/Notes |
--- | --- | ---
10 Oct 8:38 am | Subject contacted by phone, ICFS, S. |  
12 Oct 2:15 pm | Subject called with Qs. Discussed |  

Staff initials: [Initials]
Corrections

- Single line through
- Brief Reason
- Correct data
- Today’s date & initials

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What’s wrong here?

LIAR!!

37 what?
37 point what?

That’s not inches!!

Why is that blank?!
Better!

Corrected with a single line trough and initials and date!

<table>
<thead>
<tr>
<th>Vital Signs</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Pressure (sitting 5 minutes):</td>
<td>110 / 72</td>
</tr>
<tr>
<td>(Less than 120 mm Hg systolic pressure and less than 80 mm Hg diastolic pressure)</td>
<td></td>
</tr>
<tr>
<td>Systolic</td>
<td></td>
</tr>
<tr>
<td>Diastolic</td>
<td></td>
</tr>
<tr>
<td>Pulse Rate (60 to 100 beats per minute)</td>
<td>68 BPM</td>
</tr>
<tr>
<td>Respiratory Rate (12-16 breaths per minute)</td>
<td>18-15 BPM</td>
</tr>
<tr>
<td>Temperature (Taken orally, 97.8 - 99 degrees F or 36.5 - 37.2 degrees C)</td>
<td>98.0 °F</td>
</tr>
<tr>
<td>(Please round to one decimal place)</td>
<td></td>
</tr>
<tr>
<td>Height/Weight</td>
<td></td>
</tr>
<tr>
<td></td>
<td>68 in</td>
</tr>
<tr>
<td></td>
<td>152 lbs</td>
</tr>
</tbody>
</table>

*To be included in the study, the subject’s blood pressure may not exceed 120-80 mmHg.

Recorder’s Initials: KT  Date: 12/1/15
What’s wrong here?

Did this happen Dec 1st or Jan 12th?

Oh, now come on...

And why is it signed on the 5th? Dec 5th hasn’t happened yet!!
### Study Drug Administration

**Study Drug Administration**

**Single Dose over 60 +/- 5 minutes**

<table>
<thead>
<tr>
<th>Date/Start Time of Dose of Study Medication</th>
<th>01/DEC/2015 09:00</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date/End Time of Dose of Study Medication</td>
<td>01/DEC/2015 09:58</td>
</tr>
</tbody>
</table>

**Subject Weight**

- **Weight:** 74 kg
- **Date:** 12/1/15

**Total dose patient received (based on age-weight dosing schedule)**

- **40 kg or less (concentration of 0.5mg/mL):**
  - **Weight (kg):** 40.0
  - **mL/min:** 0.40
  - **mL/hr:** 24.0

- **41 kg or more (concentration of 1.67mg/mL):**
  - **Weight (kg):** 41.00
  - **mL/min:** 0.12
  - **mL/hr:** 7.4

---

**Ahh, it happened Dec 1st**

**And this is corrected properly.**

**And look, it’s even dated the same day!**

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