
# MESA-MIND Manual of Operations: Florbetaben PET

## 1. CONTACT INFORMATION

For any study-related questions, problems or issues, please contact the following resources:

- Participant eligibility or logistics: MESA-MIND MESA-MIND@wakehealth.edu
- PET acquisition or scanner specific reconstruction parameters: Email Robert Koeppe (koeppe@umich.edu)
- Scheduling tracer doses and production schedules Florbetaben/Neuraceq: Life Molecular Imaging (LMI) orders.sterling@life-mi.com, phone 800-392-2423

## 2. PET Scanner Qualification

Each site must be qualified for PET prior to scanning participants. If the PET scanner being used has already been qualified for ADNI by the PET Core (Koeppe lab, Univ. Michigan) and has not experienced any major software or hardware upgrades, re-qualification will not be required. If a new scanner must be introduced, please reach out to the PET Core for specific instructions on how to get PET scanners qualified. Your scanner will need to be qualified by the PET Core before imaging can be performed (see contact information above). Please contact koeppe@umich.edu for specific instructions on how to get PET scanners qualified.

Ideally, no hardware or software upgrades of the PET imaging system should occur during the duration of the study. In the event of such an upgrade, we ask that you inform the PET Core prior to the anticipated upgrade. Depending on the nature of the upgrade the site may be asked to repeat the phantom scans prior to scanning any additional participants.

## 3. Florbetaben (Neuraceq; Amyloid PET) Ordering

PET technologists (and in some circumstances, Study Coordinators) will need to register their contact information with Life Molecular Imaging (LMI) to place orders via their online ordering system. Please refer to **Appendix C** for detailed instructions on this process including the dose order form.

## 4. Amyloid (florbetaben) tracer injection procedures

- Have the participant use the restroom and empty their bladder.
- Allow the participant to lie comfortably in a bed or reclining chair in a room. Supply the participant with blankets/pillows as needed to maximize their comfort.
- Obtain intravenous access using a small angiocath.
- Inspect the radiopharmaceutical dose solution prior to administration and do not use it if it contains particulate matter or is discolored.
- IV injection of amyloid tracer:
    - Florbetaben (Neuraceq) 296 MBq (8.0 mCi) (minimum 5 mCi / maximum 8.8 mCi).

## 5. Participant positioning

Proper participant positioning is a key aspect of the successful completion of the PET exams. It should begin about 10 minutes before scanning begins. It is important to take the time necessary to ensure not only that the participant is properly positioned but also can comfortably maintain that position throughout the duration of the scanning session. Excessive

motion and in particular a difference in the participant's position between the emission scan and the transmission or CT scan used for attenuation correction is the single most common cause of failed studies.

- Have the participant remove any bulky items from their pockets such as billfolds, keys, etc. In addition, they should remove eyeglasses, earrings, and hair clips/combs if present. If possible, they should try and remove hearing aids also.
- Position the participant so their head and neck are relaxed. It may be necessary to add additional pads beneath the neck to provide sufficient support. Use the lasers to ensure there is little or no rotation in either plane. The head should be approximately positioned such that the PET scanning planes are parallel to the imaginary line between the external canthus of the eye and the external auditory meatus (orbitomeatal plane) and the head is centered in the sagittal plane. More important than matching the orbitomeatal plane is making sure the participant is comfortable, which will hopefully translate to less participant motion during the scan.
- Use support devices under the back and/or legs to help decrease the strain on these regions. This also will assist in the stabilization of motion in the lower body.
- Once the participant has been positioned foam pads can be placed alongside the head for additional support. Velcro straps and/or tape should also be used to secure the head position. Vacuum beanbags can also be used in this process.
- The participants should be offered a "panic button" or be reassured that someone is watching or able to hear them at all times.
- Proper positioning of the participant to get the entire head in the center of the field of view is critical to the success of the project.
- Checking the participant positioning and readjusting (if possible) the position of the participants' head should be done often throughout the study.

**6. Attenuation Correction Procedures for PET/CT Scanners**

- Standard CT acquisition parameters, but low effective mAs (~30 is typical).
- The participant must undergo the CT scan starting about 5 minutes prior to starting the PET scan. Be sure to prepare the participant so that you are ready to press "start" for the PET emission scan at the required time.

**7. Amyloid (florbetaben) PET Scan Procedures**

Adverse events (AEs) will be continuously monitored during any PET imaging session. Participants who experience an AE will not be discharged from the imaging center until the event has resolved or stabilized.

PET scan:

- Emission acquisition start time:
    - Florbetaben (Neuraceq) 90 minutes post injection
- Acquire a 20 min dynamic scan consisting of four 5-minute frames. Acquisition should start promptly at 90 minutes post injection. Scans should never be started prior to 90 minutes; and every effort must be made to start the scan on time. Scheduling a PET scan

very close in time following another study (which could run late) is not an acceptable reason for starting a scan late.

- The images will be immediately assessed for technical validity by the PET technologist and if considered inadequate due to motion or other artifact, the participant will have an additional 20 minutes of continuous imaging, collected as four 5-minute frames.

Post PET Scan:

- The participant will be requested to void after completion of each PET scan.
- Reconstruct images using parameters specific to the system used for scanning (**see Appendix A**). The same reconstruction parameters should be used for all emission scans. Upon completion of the reconstruction, review all the images to assess for artifacts.
- Image filenames should include the participant ID provided by the study coordinator.
- Archive ALL raw and processed image data including everything to reconstruct the data again if needed. It is necessary to archive and store raw and processed data at the imaging site for the duration of the project (approximately 5 years).
- Transfer reconstructed PET image data from the American College of Radiology Imaging Network (ACRIN)/TRIAD system (https://triadhelp.acr.org/) to the University of Pennsylvania within 24 hours per the procedures detailed in **Appendix B** of this MOP. Please upload only the fully corrected image set. Please refer to that chapter for instructions on account generation and image uploads. You may also reach out to Lisa Desiderio (Lisa.Desiderio@pennmedicine.upenn.edu) or Lisa Cimino (lcimino@acr.org) for assistance.
- Study Coordinator confirms that image data has been uploaded and data recorded on the form has been data entered as well within 24 hours. Study coordinator should follow-up within 3 - 4 days post scan to ensure that all imaging data has been entered. Detailed instructions on data entry of procedures forms can be found in **Appendix B**.

**APPENDIX A. SCANNER SPECIFIC RECONSTRUCTION PARAMETERS FOR GE DISCOVERY RX (HOPKINS)**

This appendix outlines the reconstruction parameters for the florbetaben scans (**GE DISCOVERY RX (HOPKINS) only)**
For questions regarding scanner specific reconstruction parameters: Email Robert Koeppe (koeppe@umich.edu)

The reconstruction parameters are as follows:

- 3D-iterative recon
- 4 iterations
- 21 subsets
- no smoothing
- 128x128 recon matrix
- 25.6 cm FoV (results in 2.0 mm voxels)
- scatter correction method (model-based)
- randoms correction method (singles)

**APPENDIX B. MESA MIND CT/PET Imaging Protocol and Acquisition Form**

**MESA MIND Protocol Appendix - Detailed CT/PET Imaging Protocol**

***Amyloid PET Brain Imaging***. Participants who enroll will complete a amyloid imaging protocol with the FDA approved [18F] Florbetaben (Neuroceq ®), which is similar to that used by the Alzheimer's Disease Neuroimaging Initiative – Study (ADNI). Participants will not receive the results from this scan unless so indicated by a clinically significant medical finding.

- Participants will report to the imaging facilities.
- Vital signs (blood pressure, heart rate, temperature) and body weight will be measured on the same day of tracer injection.
- [**18F] Florbetaben -** Participants will be injected with an intravenous bolus of approximately 8 mCi of tracer (minimum 5 mCi / maximum 8.8 mCi). This is the standard dose used in the many published clinical reports using [18F] Florbetaben. After injection, participant will wait for an uptake period of 90 minutes before the PET image acquisition begins.
- Participants will be positioned in the PET/CT scanner by trained staff. Participants will be monitored via audio micorphone and video. During PET imaging, participants must remain as still as possible and thus every effort will be made to provide for their comfort including blankets, pillows and diligent assessment. The PET brain imaging procedure is similar to that used by large multicenter imaging clinical trials. Scanning will begin with a standard low dose CT transmission scan of the head that will be used to correctly position the participant and for attenuation correction. Brain emission images will be acquired continuously for a 20 minute period as four 5-minute frames. The images will be immediately assessed for technical validity by the PET technologist and if considered inadequate due to motion or other artifact, the participant will have an additional 20 minutes of continuous imaging, collected as four 5-minute frames.
- From the time of tracer injection until after the imaging session is complete, participants will be observed continuously for signs of adverse events or serious adverse events. The injection site will be observed for excessive inflammation or damage to the surrounding tissue.
- A physician or a person designated by the physician with appropriate training and experience will be present during the tracer injection and to approve discharge of the participant from the PET suite.

# Exam 7
## Brain PET Acquisition

Participant ID #: ☐☐☐☐☐☐☐ Acrostic:* ☐☐☐☐☐☐☐

**Do not enter into PET software*

Technician ID: ☐☐☐☐ Date: ☐☐ / ☐☐ / ☐☐☐☐
Month Day Year

1. PET tech ID: _____

2. Time of today's scanner QC: ☐☐ : ☐☐ ○ AM ○ PM

**Participant Information**

3. Sex:
- ○ Male
- ○ Female

4. Age: _____

**Pre-scan Vitals**

5. Blood pressure: _____ / _____

6. Pulse: _____ bpm

7. Weight: _____ lbs

8. Temperature: _____ $^{O}$F

Tracer: ○ (11C) PiB
○ (18F) florbetaben

9. Dose: _____ mCi

10. Dose assay time: ☐☐ : ☐☐ ○ AM ○ PM

11. Dose injection time: ☐☐ : ☐☐ ○ AM ○ PM

12. Residual: _____ mCi

12.1 Residual Assay Time: ☐☐ : ☐☐ ○ AM ○ PM

**Post-injection Vitals**

13. Blood pressure: _____ / _____

14. Pulse: _____ bpm

15. Was appropriate time allowed for tracer uptake?
- ○ No
- ○ Yes, 40 minutes for (11C) PiB
- ○ Yes, 90 minutes for (18F) Florbetaben

16. Scan start time: ☐☐ : ☐☐ ○ AM ○ PM

17. Any variations from protocol during tracer uptake?
- ○ Yes → If yes, note below (Q29)
- ○ No

18. Was the scan completed?
- ○ Yes
- ○ No → If no, note below (Q29)

**Post-scan Vitals**

19. Blood pressure: _____ / _____

20. Pulse: _____ bpm

Additional measurements, if necessary:

21. Blood pressure: _____ / _____

22. Pulse: _____ bpm

23. Blood pressure: _____ / _____

24. Pulse: _____ bpm

25. Injection site location and observations:

_____

26. Participant encouraged to void and drink plenty of fluids the rest of the day?

- ○ Yes
- ○ No

27. PET technician signature: _____

28. Notes: _____

_____

CALL STUDY STAFF PRIOR TO RELEASING PARTICIPANT. *[Insert site contact name and phone]*

## APPENDIX C. Florbetaben Instructional Slides and Dose Order Form

# Mesa Mind- Florbetaben Kick-Off

**Hillary J. Rouse, PhD**
**Richard Keegan, PhD**
**Medical Science Liaison, Life Molecular Imaging**
**Monday, April 03, 2023**

Life HEALTH CARE Molecular Imaging

# Life Molecular Imaging Team

| Function | Contact | Email | Direct Phone | Location | |
|---|---|---|---|---|---|
| **Medical Science Liaison** | **Richard Keegan, PhD** | **r.keegan@life-mi.com** | **(203)450-3652** | **TN** | **MSL** |
| Medical Affairs Project Manager | **Jesse Blom, MBA** | j.blom@life-mi.com | (646)670-6609 | NY | Operations |
| Medical Affairs Contracts Manager | **Nicole Davis** | n.davis@life-mi.com | | CA | Contracts |
| Director – Global Supply Chain | **Amit Kumar** | a.kumar@life-mi.com | (856)207-4224 | NJ | |
| Chemistry, Manufacturing, and Controls (CMC) Manager | **James Havey, PhD** | j.havey@life-mi.com | | CT | |
| Chief Medical Officer | **Andrew Stephens, MD** | a.stephens@life-mi.com | | Berlin | |
| Head of Medical Affairs | **Matt Trifilo, PhD** | m.trifilo@life-mi.com | | CA | |

# Sofie Information

| Location | Address | Main Phone | FBB Production Schedule |
|---|---|---|---|
| **Sterling, VA** | 21000 Atlantic Blvd<br>#730<br>Sterling, VA 20166 | (703)787-4075 | Tuesday<br>Wednesday<br>Thursday |

# Neuraceq™

# Neuraceq™ (florbetaben F18 injection) – Indications & Usage

- Neuraceq is indicated for Positron Emission Tomography (PET) imaging of the brain to estimate β-amyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for Alzheimer's Disease (AD) and other causes of cognitive decline
- A negative Neuraceq scan indicates sparse to no amyloid neuritic plaques and is inconsistent with a neuropathological diagnosis of AD at the time of image acquisition; a negative scan result reduces the likelihood that a patient's cognitive impairment is due to AD
- A positive Neuraceq scan indicates moderate to frequent amyloid neuritic plaques; neuropathological examination has shown this amount of amyloid neuritic plaque is present in patients with AD, but may also be present in patients with other types of neurologic conditions as well as older people with normal cognition
- Neuraceq is an adjunct to other diagnostic evaluations

# Neuraceq™ – Posology and Method of Administration

- A PET scan with Neuraceq should be requested by clinicians experienced in the clinical management of neurodegenerative disorders
- Neuraceq dosing as per product label
  - Target dose 300 MBq Neuraceq (up to 8.1 mCi)
  - Administer as a single dose over 1 minute (6 sec/mL)
  - In a total volume of up to 10 mL
  - **Do not** dilute Neuraceq
- Image acquisition and processing as per product label
  - Acquire PET images over 15 to 20 minutes starting 45 to 130 minutes after Neuraceq injection (or as described in the clinical study protocol if different)
  - A visual binary read (positive or negative) will be determined according to criteria established by Life Molecular Imaging to categorize subjects as amyloid-positive or amyloid-negative.

# Neuraceq™ – Important Safety Information

**Risk for Image Interpretation and Other Errors**

- Neuraceq can be used to estimate the density of β-amyloid neuritic plaque deposition in the brain. Neuraceq is an adjunct to other diagnostic evaluations. Neuraceq images should be interpreted independent of a patient's clinical information. Physicians should receive training prior to interpretation of Neuraceq images. Following training, image reading errors (especially false positive) may still occur.
- Additional interpretation errors may occur due to, but not limited to, motion artifacts or extensive brain atrophy.

**Radiation Risk**

- Administration of Neuraceq, similar to other radiopharmaceuticals, contributes to a patient´s overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk of cancer. It is important to ensure safe handling to protect patients and health care workers from unintentional radiation exposure.

# Neuraceq™ – Important Safety Information (cont.)

**Most Common Adverse Reactions**

- In clinical trials, the most frequently observed adverse drug reactions in 872 subjects with 1090 Neuraceq administrations were injection/application site erythema (1.7%), injection site irritation (1.1%), and injection site pain (3.4%).

**Radiation dose**

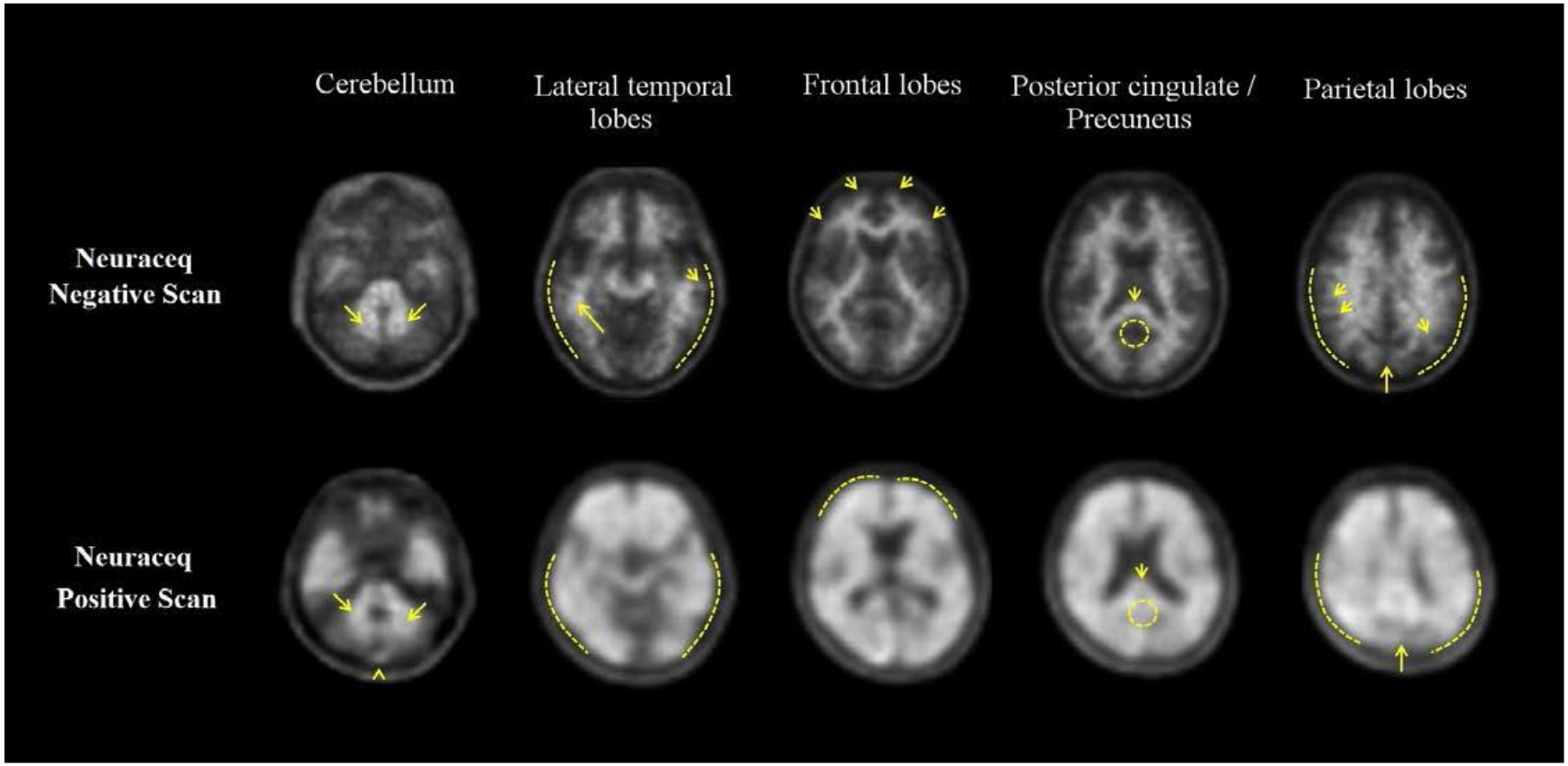
- Mean effective radiation dosage from 300 MBq approved administration of Neuraceq is 5.8 millisievert (mSv)
- The organs receiving notable radiation exposure include the gallbladder, urinary bladder, upper large intestine wall, lower large intestine wall, small intestine and liver

**After administration of Neuraceq**

- Avoid use in a breastfeeding mother or have the mother temporarily interrupt breastfeeding for 24 hours after exposure to Neuraceq.

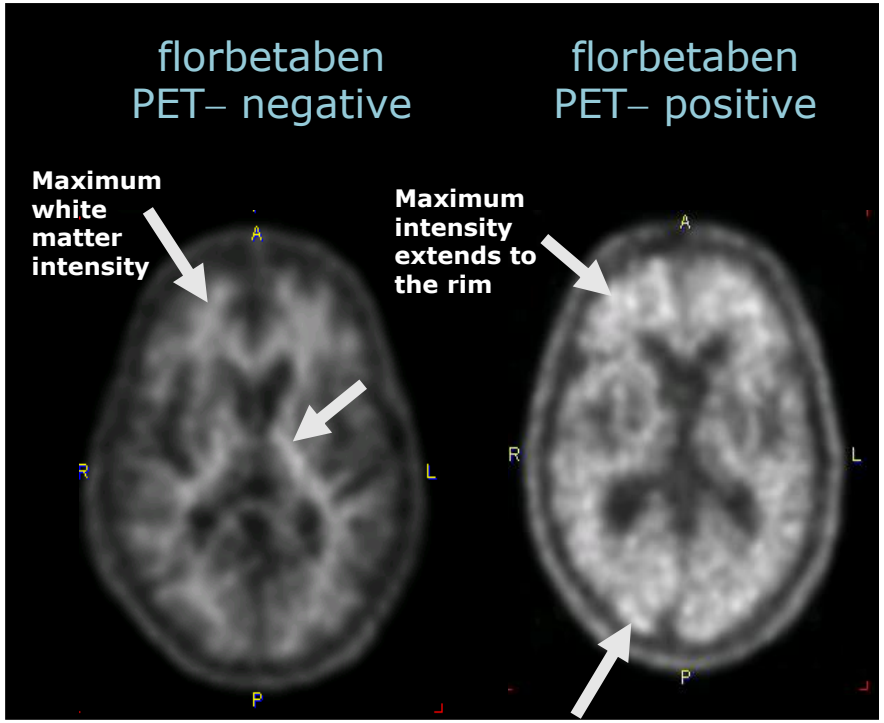
# Visual Assessment of Neuraceq® (florbetaben F18 injection) Scans

## Systemic visual interpretation: gray scale, binary assessment




Neuraceq® US [package insert]. Life Molecular Imaging. Matran, Switzerland: S.A.; April 2021

# Visual Assessment of Neuraceq® (florbetaben F18 injection) Scans




- Images should be read in transaxial orientation
- Grayscale or inverse grayscale
- Four target regions:
  1. Frontal cortex
  2. Posterior cingulate/precuneus
  3. Lateral temporal cortex
  4. Parietal cortex
- Gray matter signal intensity compared to maximum white matter intensity
- If one target region is β-amyloid positive, then they entire brain is "positive"

Adapted from: Neuraceq® US [package insert]. Life Molecular Imaging. Matran, Switzerland: S.A.; April 2021

# Neuraceq™ – Safety Reporting Requirements

The PI shall report to LMI safety relevant information:

By e-mail: PHV@life-mi.com or By Fax: +49 (0) 30 46 11 24 629

- Immediately, within 2 business days after awareness of event, all cases concerning **Serious Adverse Events** (SAE), independent of their causal relationship to the TAU or Neuraceq tracer that occur within 5 days after injection;
- Within 2 business days, all cases concerning **Adverse Drug Reactions** (ADRs);
- Within 2 business days, even if no ADR/SAE occur "**Extraordinary Situations**" that come to the attention of the PI (such as exposure during pregnancy, exposure during breastfeeding, data on use in Children, reports on compassionate use/named patient use, lack of efficacy or effect, report of suspected transmission of infectious agents, reports of Overdose (accidental or intentional), abuse of Product, misuse of product, reports of Medication Error, drug exposure via mother or father or other, occupational exposure). Please see contract for further details.
- Any communication concerning safety related information to regulatory authorities or ethics committees including but not limited to:
  - Annual Safety Reports/relevant parts of IND reports for the study;
  - Any other safety related reports, issues and queries that are either raised by or communicated to the regulatory authorities or ethics committees.
- Within 48 hours, any quality issue (technical complaint) regarding the product.

# First Contact Sheet (Neuraceq)

- All communication with LMI will be in English.
- Safety Event information will be provided to LMI using the attached 1st Contact Sheet, or **alternatively the Council for International Organizations of Medical Sciences (CIOMS) form or other Institutional reporting form may be used as long as all required information is included**.
- All Safety Events will be transferred via fax or secure email.
- All Safety Event for Exchange will be sent to gra@life-mi.com by Sponsor. All reports must contain, but not limited to, the following:
- name and contact information of the reporter
- description of the reported safety relevant information
- patient identified by one or more of the following:
  - patient initials
  - patient number
  - age
  - sex
- Additional information requested if available:
- name and batch number of the study drug(s) (including administration time point and date) if available
- Investigator assessment of study drug causality.

**Original Reporter / Source**

| | |
|---|---|
| ☐ Physician<br>☐ Pharmacist<br>☐ Patient / Consumer<br>☐ Health Authority | ☐ Registry<br>☐ Other:<br>…… |

**Country of Occurrence**

**Original Reporter Information**

| | |
|---|---|
| **Name** | |
| **Address** | |
| **Tel. / Mobile** | |
| **Email** | |
| **Profession** | |

**Suspect Drug(s)**

| **Suspect Drug(s)** (Please specify brand name if known) | **Activity at time of injection** | **Batch number** | **Route** | **Last time applied prior to event** | **Indication** | **Action Taken Towards Drug(s)** (e.g. discontinuation etc.) |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |

**Patient Information**

| **Patient Initials** | **Birth Date or Age** | **Gender** ☐ Male ☐ Female |
|---|---|---|
| | | |

**Adverse events or other safety relevant information**

| **Event(s)** | **Start date / time** | **End date / time** |
|---|---|---|
| | | |
| | | |
| | | |

| | | | |
|---|---|---|---|
| Immediately life-threatening | ☐ Yes ☐ No | Hospitalised (or hospitalisation prolonged) | ☐ Yes ☐ No |
| Death | ☐ Yes ☐ No | Permanent damage or disability | ☐ Yes ☐ No |
| Congenital / birth defect | ☐ Yes ☐ No | | |

**Person filling in this report**

| | |
|---|---|
| **Name** (print) **/ Company** | |
| **Tel. / Mobile** | |
| **Email** | |
| **Report received at (date and time)** | |

**Date** _____ **Signature** _____

# Neuraceq™
# – Supply Chain / Ordering / Logistics

- Primary Contact: Amit Kumar (Life Molecular Imaging) Supply Chain
- Sofie and Life Molecular Imaging relationship
- Dose dispensed +/- % limits (10%)
- Calibration times (out of door plus travel plus 30 min)
- Equipment (Cases/Shields) (lead lined container, pre-filled syringe)
- Service related issues (Delivery and Quality Assurance) – local Sofie Pharmacy

# Neuraceq™– Ordering Doses

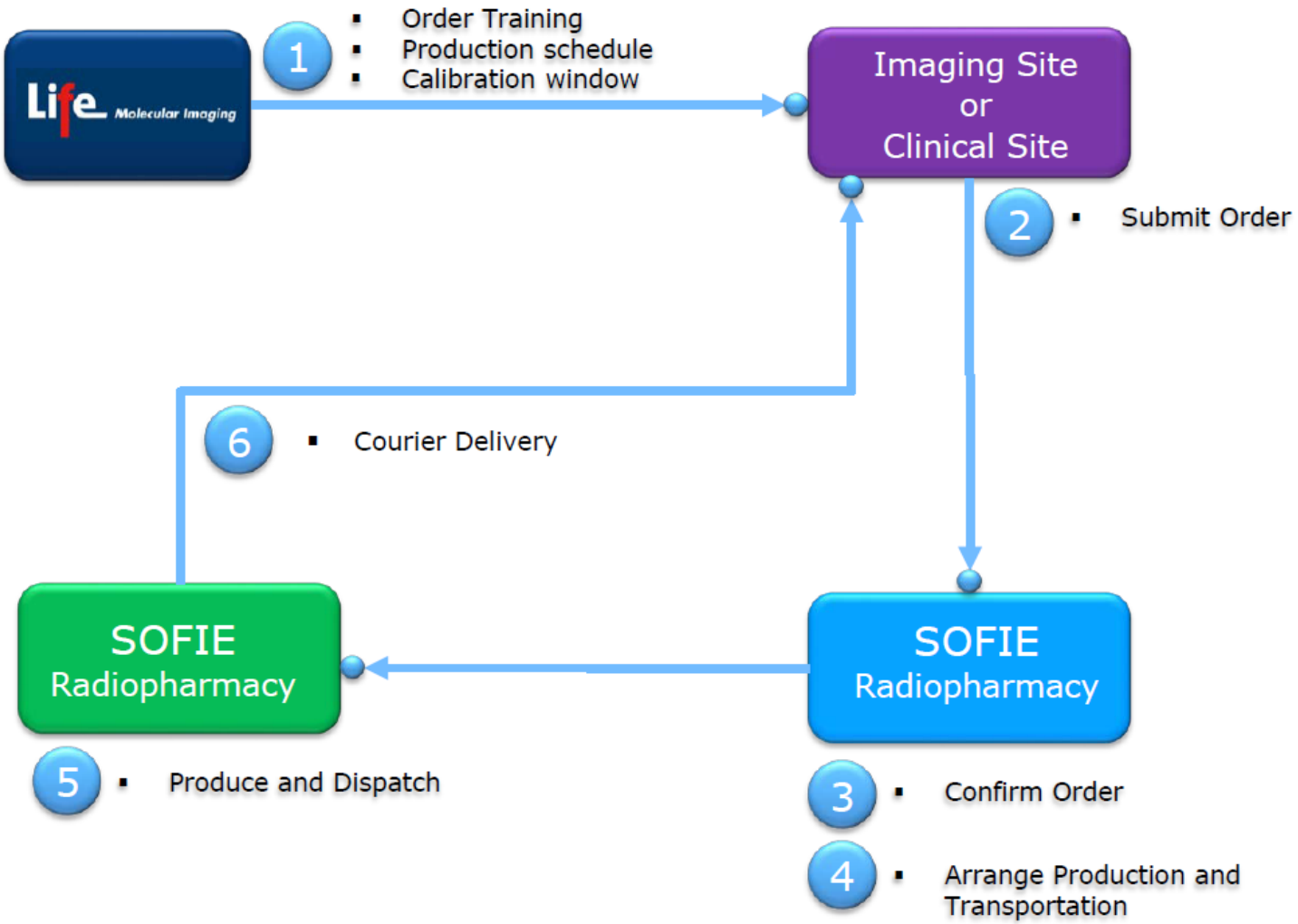
- Neuraceq™ dose orders can be placed by:
  - Printing and Faxing a completed dose Order Form to a predefined number
  - **Emailing the completed Order Form**

  *All the above info is PREFILLED in SECTION 1 of the Order Form.*

- A confirmation for the received order will be sent if required.
- Dose availability may vary, based on location, day and calibration times.
- A **Production Schedule** will be provided at regular intervals or whenever there is a change to facilitate scheduling of study participants.
- The **Injections Window** for scheduling patients will be communicated to site.


**Please provide Life Molecular Imaging (Supply chain Manager) the email addresses of the individuals that need to receive production schedule updates**

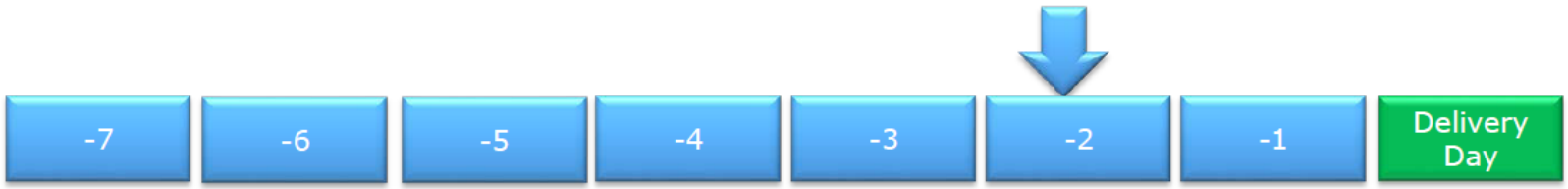
# High Level Ordering Process



# Ordering Deadlines

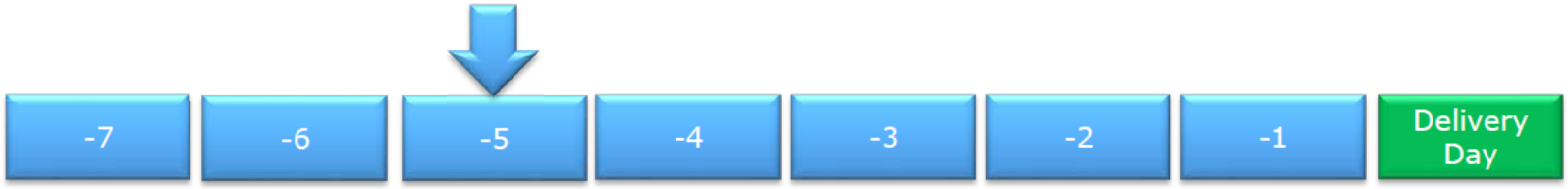
## Road Transport

Place Dose Orders by 14:00 local time **2 business days** in advance of required delivery day




## Flight Required

Place Orders by 14:00 local time **5 business days** in advance of required delivery day



# Dose Cancellation Policy

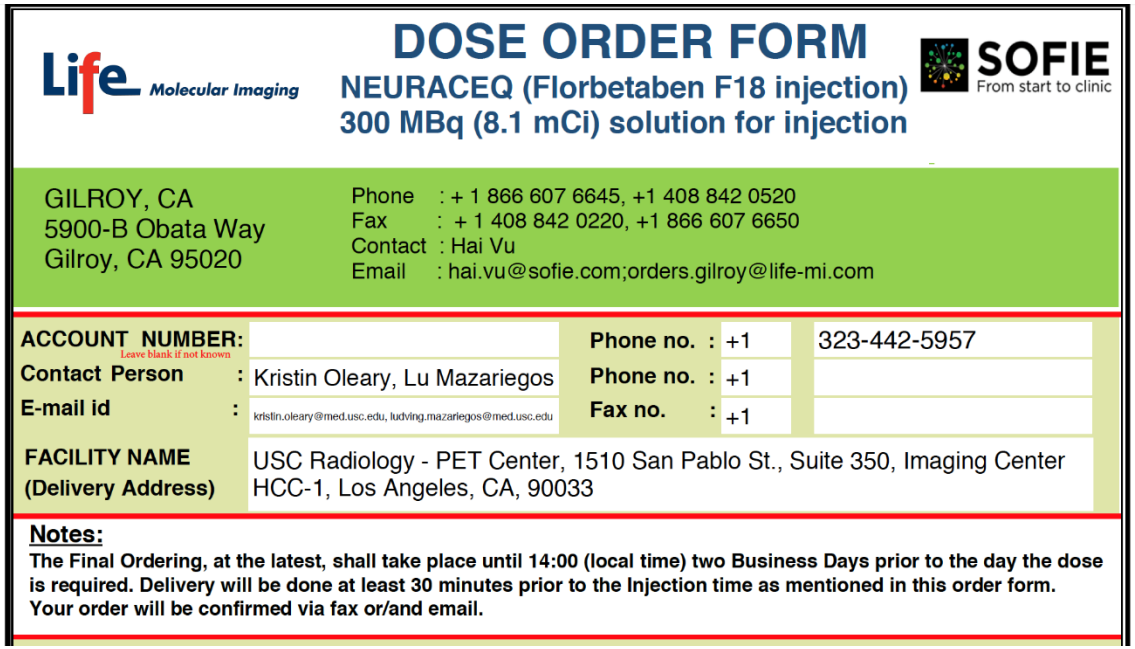
- Life Molecular Imaging's standard order **cancellation is two business days** prior to scheduled delivery for road transportation and **four business days** prior to scheduled delivery for flight transportation.

- Cancellation requests must be made to SOFIE manufacturing pharmacy by phone with follow up in writing.

- **Any cancellations made after these time points will be invoiced to study site.**

# Neuraceq™ Dose Order Form

1. The form is a sample form.
2. This will be prefilled and released after we get the details for the site.
3. Required details:
   1. Delivery address
   2. Contact person and contact details
   3. Any special instructions.



Life Molecular Imaging

**DOSE ORDER FORM**

**NEURACEQ (Florbetaben F18 injection)**
**300 MBq (8.1 mCi) solution for injection**

SOFIE From start to clinic

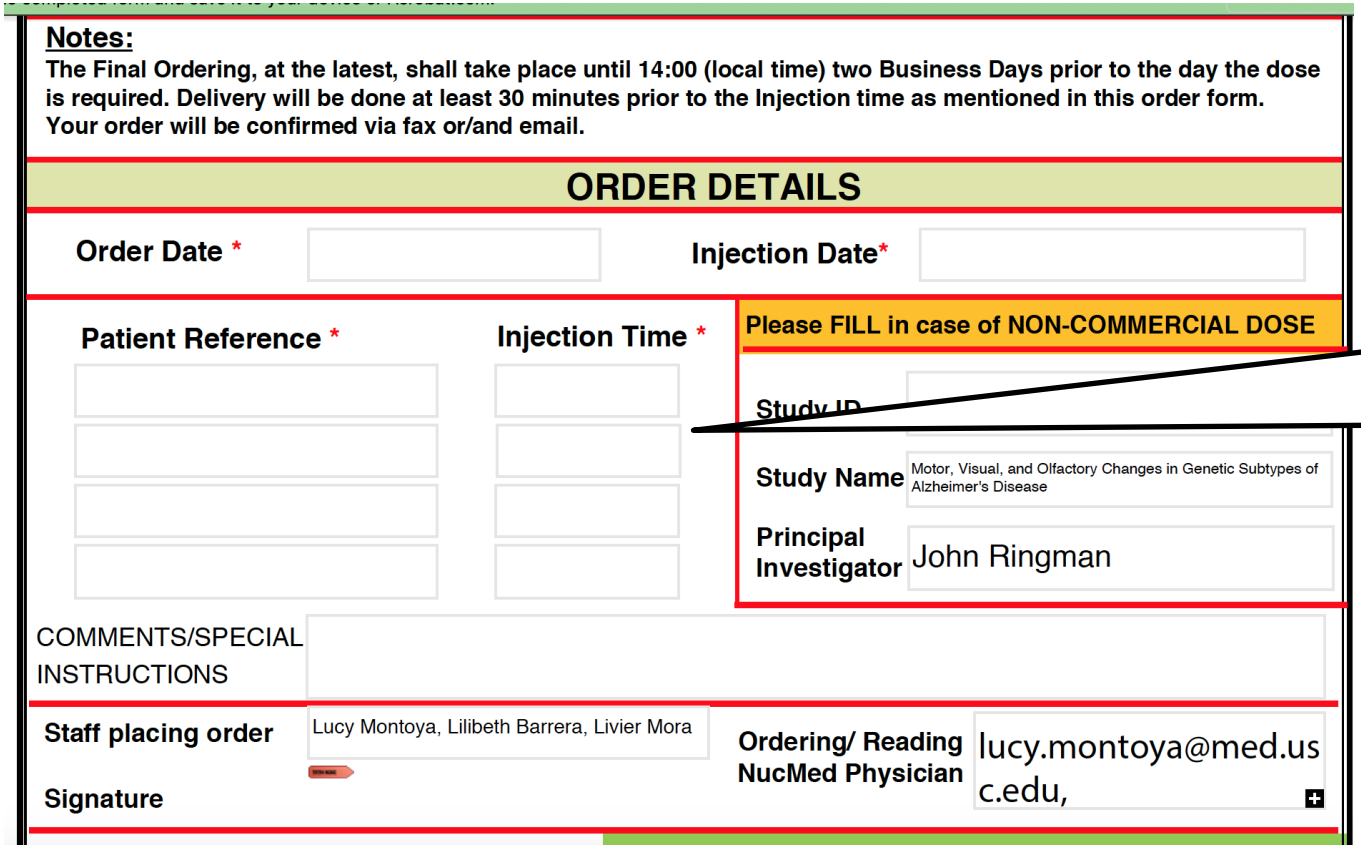
GILROY, CA
5900-B Obata Way
Gilroy, CA 95020

Phone : + 1 866 607 6645, +1 408 842 0520
Fax : + 1 408 842 0220, +1 866 607 6650
Contact : Hai Vu
Email : hai.vu@sofie.com;orders.gilroy@life-mi.com

| | | | |
|---|---|---|---|
| **ACCOUNT NUMBER:** Leave blank if not known | | **Phone no. : +1** | 323-442-5957 |
| **Contact Person :** | Kristin Oleary, Lu Mazariegos | **Phone no. : +1** | |
| **E-mail id :** | kristin.oleary@med.usc.edu, ludving.mazariegos@med.usc.edu | **Fax no. : +1** | |
| **FACILITY NAME (Delivery Address)** | USC Radiology - PET Center, 1510 San Pablo St., Suite 350, Imaging Center HCC-1, Los Angeles, CA, 90033 | | |

**Notes:**
**The Final Ordering, at the latest, shall take place until 14:00 (local time) two Business Days prior to the day the dose is required. Delivery will be done at least 30 minutes prior to the Injection time as mentioned in this order form. Your order will be confirmed via fax or/and email.**

# Neuraceq™
# Dose Order Form (*variable*)



**Notes:**
**The Final Ordering, at the latest, shall take place until 14:00 (local time) two Business Days prior to the day the dose is required. Delivery will be done at least 30 minutes prior to the Injection time as mentioned in this order form. Your order will be confirmed via fax or/and email.**

**ORDER DETAILS**

**Order Date** *

**Injection Date***

**Patient Reference** *

**Injection Time** *

**Please FILL in case of NON-COMMERCIAL DOSE**

**Study ID**

**Study Name** Motor, Visual, and Olfactory Changes in Genetic Subtypes of Alzheimer's Disease

**Principal Investigator** John Ringman

COMMENTS/SPECIAL INSTRUCTIONS

**Staff placing order** Lucy Montoya, Lilibeth Barrera, Livier Mora

**Signature**

**Ordering/ Reading NucMed Physician** lucy.montoya@med.usc.edu,

Section 3 of Order Form: need to complete before placing order

# What you need to do now


1. Check the pre-filled order form you are provided with. Ensure the pre-filled information is correct. Make corrections if necessary.


2. Provide SOFIE (contact details on the order form) with the contact details of the individuals that need to receive the following:

    - Order confirmations email addresses or Fax


3. Provide a.kumar@life-mi.com/r.keegan@life-mi.com with a list of the email addresses of the individuals to receive updates to the production schedules.

# Project Management

- Life Molecular Imaging primary contacts
- Coordinate regular meeting with PI and/or Study Coordinators (progress report, adverse event reporting, special requests concerns, patient scheduling)
- Communicate progress to Life Molecular Imaging's Project Manager, notably through the Monthly Reporting Form (*see an example next slide*)

# Project Management (Monthly Report Form)

**Research Monthly Report Form**

Please submit copy to:
**Elisa Canzoneri, e.canzoneri@life-mi.com**, Medical Science Liaison - Medical Affairs, Life Molecular Imaging

| **Main Project Information:** | |
|---|---|
| • Project Title | Motor, Visual, and Olfactory changes in genetic subtypes of Alzheimer's Disease |
| • Name of Institution | USC |
| • Name of Principal Investigator | Dr. John Ringman |
| • Contact Date | Enter date |

| **Study Progress:** | |
|---|---|
| • Study Phase | Not Yet Recruiting X Recruiting ☐ Recruitment Complete ☐ |
| • Total Scanned (Cumulative) | Type here |
| • Number Scanned this month | Type here |
| • **Comments**: | |

| **Doses:** | |
|---|---|
| • Number of Doses Ordered this month | Type here |
| • Number of Doses required next month (indicate if estimated) | Type here |
| • **Comments**:<br>Type here | |

| **Adverse Event Reporting:** | |
|---|---|
| • **Adverse Events** | |
| • Any Adverse Events | ☐ Yes ☐ No<br>Choose a date.<br>If yes, please ask Sponsor to complete the AE Form and provide this to you. |

**Life Molecular Imaging Inc.**
75 State Street
Floor 1
Boston, MA 01209, USA

**Email:** info@life-mi.com

**Web:** www.life-mi.com

# THANK YOU

# DOSE ORDER FORM

## NEURACEQ (Florbetaben F18 injection)
## 300 MBq (8.1 mCi) solution for injection

Life Molecular Imaging

SOFIE From start to clinic


Sterling, VA
100 Executive Dr, Ste 3
Sterling, VA 20166

Phone : + 1 800 392 2423, +1 703 787 4075
Fax : + 1 703 478 0499
Contact : Nasrin Pourkiani
Email : orders.sterling@life-mi.com


| | | | | |
|---|---|---|---|---|
| **ACCOUNT NUMBER:** Leave blank if not known | | **Phone no. :** | +1 | 410-897-2167, 704-231-3996 |
| **Contact Person :** | Hailey Maranto, Noh Mebrahtu, Shika Inala, Jeffrey Shin | **Phone no. :** | +1 | 240-586-0066, 954-683-2183 |
| **E-mail id :** | hmarant1@jhu.edu nmebrah1@jhmi.edu sinala1@jhmi.edu jshin64@jhu.edu | **Fax no. :** | +1 | |
| **FACILITY NAME (Delivery Address)** | Johns Hopkins Hospital<br>600 N. Wolfe St, Nelson B1175 PET CTR<br>Baltimore, MD 21287 | | | |

**Notes:**

**The Final Ordering, at the latest, shall take place until 14:00 (local time) two Business Days prior to the day the dose is required. Delivery will be done at least 30 minutes prior to the Injection time as mentioned in this order form. Your order will be confirmed via fax or/and email.**

## ORDER DETAILS

**Order Date *** 

**Injection Date*** 

**Patient Reference *** 

**Injection Time *** 

**Please FILL in case of NON-COMMERCIAL DOSE**

| | |
|---|---|
| **Study ID** | RC111 |
| **Study Name** | " MESA-MIND: Multi-Ethnic Study of Atherosclerosis (MESA) Multisite Study of Alzheimer ' s Disease |
| **Principal Investigator** | Timothy Hughes |

COMMENTS/SPECIAL INSTRUCTIONS

**Staff placing order**

**Signature**

**Ordering/ Reading NucMed Physician**

## FOR RADIOPHARMACY USE

**Order Entered By**

**COMMENTS**

Orders.Sterling@life-mi.com