PET Technical Operations Manual: [^{18}F] AV-133

Document Version	Final v3.0; 20-Aug-2020
Sponsor for PPMI Clinical study	Michael J. Fox Foundation
Protocol Identifier	002
Protocol Version	Version 1.0; 08-Apr-2020
Protocol Description	The Parkinson's Progression Markers Initiative (PPMI) 2.0 Clinical - Establishing a Deeply Phenotyped PD Cohort
Sponsor for [^{18}F] AV-133 study	Institute for Neurodegenerative Disorders
Protocol Identifier	004
Protocol Version	Version 2; 19-Jun-2020
Protocol Description	Early Longitudinal Imaging in Parkinson's Progression Markers Initiative Using [^{18}F] AV-133 and DaTscan™ (PPMI Early Imaging 2.0)
Investigational Product	[^{18}F]AV-133

Document Approval

Sponsor Signature Page

The signatures below, in addition to the other designated signature(s), indicate that this document is accepted and approved for implementation.

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Table of Contents

1 Overview

The Imaging Core Lab is Invicro, a Konica Minolta Company (Invicro) based in New Haven, Connecticut, USA. In conjunction with the study sponsor, Invicro will provide the imaging center with any technical support necessary to ensure optimal imaging is achieved. Invicro will be responsible for imaging center evaluation, qualification, and training as well as, receipt, quality control (QC), query, and data management of imaging data and corresponding scan acquisition documentation.

Participating clinical site imaging centers will acquire images according to the trial-specific process standards detailed within this manual. Imaging centers will submit images and corresponding data (image data) to Invicro using iPACS, as the preferred method. iPACS enables the secure, controlled, and efficient submission of image data, in addition, to serving as the portal for query resolution. Before data from participants may be acquired, Invicro will train each imaging center on the image acquisition requirements, and the image data submission and query resolution processes.

1.1 Purpose of the Technical Operations Manual

This Technical Operations Manual (TOM) describes the technical components of [18F] AV-133 positron emission tomography (PET) imaging used in the Parkinson's Progression Markers Initiative (PPMI) Early Imaging 2.0 study, which is a companion study of the larger PPMI 2.0 Clinical study (Protocol 002). This TOM is supplemental to the two approved PPMI 2.0 Clinical single-photon emission computed tomography (SPECT) and magnetic resonance imaging (MRI) TOMs. Please refer to the PPMI 2.0 Clinical SPECT and MRI TOMs for further details on the following:

- Imaging center training and setup
- Participant safety and adverse events
- Archiving of images and corresponding data
- Submission of image data to Invicro
- Query receipt and resolution process
- SPECT and MRI imaging details

1.2 Trial Design

The current study is a longitudinal, multi-center study to assess progression of DaTscan and [18F] AV-133 imaging in Parkinson's Disease (PD) participants for at least 18 months. This study will be considered a companion study to the larger PPMI 2.0 Clinical study. Participants will be enrolled with eligibility criteria similar to that of the PPMI 2.0 Clinical study. Approximately 50 PD participants will be recruited from up to 5 clinical sites. All participants will be comprehensively assessed at baseline and every six months thereafter. Active participants transitioning from the Early Imaging 1.0 study will receive 3 [18F] AV-133 PET scans. Newly enrolled participants in the Early Imaging 2.0 study will receive 4 [18F] AV-133 PET scans. For further imaging details, see Schedule of Assessments (Section 1.3).

1.3 Schedule of Assessments

Your imaging center may scan your first participant following completion of all training and approval requirements. After the scan from the first participant is approved, scanning for the remainder of the participants may begin according to the protocol schedule of assessments.

- For transitioning participants from Early Imaging 1.0, [18F] AV-133 PET imaging will be performed at 3 time points.
- For newly enrolled participants, [18F] AV-133 PET imaging will be performed at baseline and 3 additional time points.
- [18F] AV-133 PET scans and corresponding imaging documents must be submitted to Invicro within 24 hours of image acquisition.

Table 1: Schedule of PET Assessments

Scan	Transitioning participants from Early Imaging 1.0	Newly enrolled participants for Early Imaging 2.0
Scan 1 (Day 0) [a]	-	Baseline
Scan 2 (Visit 02)	6 months (+/- 45 days)	6 months (+/- 45 days)
Scan 3 (Visit 04)	12 months (+/- 45 days)	12 months (+/- 45 days)
Scan 4 (Visit 05)	18 months (+/- 45 days)	18 months (+/- 45 days)
Premature Withdrawal Visit	Premature Withdrawal [b]	Premature Withdrawal [b]

[a] Subjects transitions from early Imaging 1.0 have had a baseline [18F] AV-133 PET scan as part of the previous study and do not require a repeat baseline scan.
[b] Please note, in the event a participant withdraws from the study early, an [18F] AV-133 PET scan should only be collected if not done in the last three months.

2 Technical Binder

The imaging center will receive a link to an electronic technical binder containing all essential imaging study documents including, but not limited to, a copy of this TOM, the training presentation, radiopharmaceutical information, and key Invicro contact information. These documents are to be printed and made available to any staff which will need access to this information. Additionally, Invicro recommends each imaging center file all study documents that have been submitted, and all study related communications (eg, emails or faxes).

Please note: Study related documents may be updated throughout the trial and will be distributed to your imaging center.

3 Scan Identification (Naming Convention)

It is very important that the imaging center uses a standard file naming convention so that all scans can be easily identified by Invicro. The participant naming convention will be provided by the Clinical Site personnel when scheduling the PET visit.

The site number is assigned to the clinical sites in the trial, not the imaging centers. Therefore, imaging centers that are receiving referrals from several clinical sites will need to use the clinical site number associated with the site the participant is being referred from, as well as on the paperwork and in the naming of the scans when transmitting data to Invicro. The clinical site number in this trial is comprised of 3 digits.

Participants transitioning from the Early Imaging 1.0 study will maintain the previously assigned 4 or 5-digit Participant ID. Participants newly enrolled in Early Imaging 2.0 will be assigned a 6-digit Participant ID.

Please note: the 4, 5 or 6-digit Participant ID number should be populated in both the Participant Name and ID fields with the Date of Birth arbitrarily populated with 01-Jan-1970 when setting up an acquisition on the scanner or during the de-identification of the scan file.

4 [18F] AV-133 Radiotracer Information

4.1 [18F] AV-133 Dose Ordering

Invicro will be coordinating [18F] AV-133 dose ordering and distribution. Training regarding dose ordering and receipt procedures along with the necessary dose request forms will be provided or overseen by Invicro. As part of the dose ordering training, imaging center staff will be made aware of production schedules and approximate time of dose delivery and product expiry time to facilitate scheduling with the clinical staff. Questions regarding dose ordering or receipt procedures should be directed to Invicro.

4.2 [18F] AV-133 Dose Preparation and Administration

The [18F] AV-133 dose will be provided to the imaging center in a single or multi-dose vial. It is the responsibility of the imaging center to ensure that they have the necessary equipment for radiopharmaceutical injection.

[18F] AV-133 doses may be dispatched from the production site before QC of the radiotracer is completed (ie, shipped under quarantine). Therefore, [18F] AV-133 must not be administered before confirmation has been received via a Quality Assurance (QA) Release document from the manufacturer verifying the dose(s) meets the Product Quality Specification Limits.

4.2.1 [18F] AV-133 Release Form / Dosing Guide Contents

For each radiotracer shipment, a Release Form / Dosing Guide (Appendix 2: [18F]AV-133 Release Form / Dosing Guide (Example)) will be sent to a designated site contact via email or fax, regarding dose specifications.

The Release Form includes notification that the dose has completed QA Release, verifying it has met cGMP drug product safety requirements and all expected specifications. The designated site contact will complete the section to acknowledge receipt of the radiopharmaceutical.

The Dosing Guide will detail the time/date specific tracer volume (mL) to draw in order to achieve the target dose, taking into account the expiration time of the radiopharmaceutical.

Please note: A Release Form / Dosing Guide will accompany each dose to be injected with label(s) for each subject if multiple doses are ordered for a given day.

4.2.2 [18F] AV-133 Dosing Administration After Receiving the Dosing Guide

Important Reminders:

- There is no requirement for participants to fast prior to [18F] AV-133 injection.
- Women of childbearing potential must have a negative urine pregnancy test performed on the day of injection (prior to injection).
- Obtain the participant's weight and document these results on the PET acquisition document.
- Vital signs (supine pulse rate and supine blood pressure) will be obtained before the administration of [18F] AV-133 (5 min ± 1 min prior to injection).
- Vital signs (supine pulse rate and supine blood pressure) will be obtained 15 minutes (± 5 minutes) post administration of [18F] AV-133.

A single IV bolus of 222 MBq (6 mCi) (± 10%) of [18F] AV-133 will be administered through an intravenous catheter. The injection is followed by an intravenous flush of 15 mL to 20 mL of normal saline (0.9% sodium chloride). The activity of the [18F] AV-133 must be assayed using a dose calibrator prior to injection. For accurate determination of the amount of activity, the empty syringe should be refilled to the same volume as the injection and re-assayed immediately following injection with the assay amounts and times recorded in the appropriate fields when uploading through the web submission portal.

The label for the dose drawn and injected (ie, 1 shield label) must be affixed to the allotted space on the Dosing Guide (Appendix 2: [18F]AV-133 Release Form / Dosing Guide (Example)), which will then be sent to Invicro through iPACS

The dose shipping container, along with the lead or tungsten shield ("pig") the vial was received in, should be returned. The tungsten shield should NOT contain the dose vial. The radiation label located on the exterior of the shipping container must be turned over to side B. If an extra label is provided in shipping container, keep it for records or deface and discard per your internal processes. DO NOT send back any additional labels.

Please refer to the most current version of the Radiopharmaceutical Supply Guidance Document (RSGD) for more detailed information on dose procedures.

Follow your facility's standard processes for documentation of information regarding the participant and scan procedure. Information requested by Invicro during the submission process will include, but is not limited to, participant weight, dose activity assays, times of assays, date and time of injection and date and time of scan. An example of the electronic data submission form with requested information is provided in the appendices of this document.

5 [^{18}F] AV-133 PET Imaging Procedures

5.1 PET Acquisition Protocol

Each participant will undergo a total of 10 minutes (2x5 minute acquisition) of serial PET imaging starting 80 minutes (± 5 minutes) post injection. A scan for attenuation correction should be performed prior to or immediately following the emission sequence. Participants should be encouraged to void prior to being positioned.

Scanning Procedure:

- Approximately 70 minutes post injection, have the participant void, and position the participant in the scanner
- Ensure the entire brain is within the field of view (FOV) and that the participant is immobilized and comfortable
- Acquire the non-diagnostic computed tomography (CT) or isotope transmission scan for attenuation correction
- Begin the emission scan 80 minutes post injection (targeting ± 5 minute)
- Scan the participant for 10 minutes (2 frames x 5 minutes)

5.2 PET Reconstruction Protocol

PET images will be corrected for attenuation, random coincidences, scatter & decay, and reconstructed in a manner that allows for harmonization of the data across varying PET imaging scanners. The reconstruction will be performed using an approved protocol that utilizes an iterative/RAMLA (Row-Action Maximum-Likelihood Algorithm) reconstruction method. Imaging data submissions are required to be transferred with and without post filtering applied.

For all sites, the reconstructed images need to be in quantitative units such as SUV, Bq/ml, kBq/cc, etc. Reconstruction protocols will have some variations depending on scanner manufacturer and software version. All parameters will be reviewed and approved by Invicro as part of site qualification.

It is important that participants are imaged on the same scanner throughout their participation in the Early Imaging 2.0 companion study and the larger PPMI 2.0 Clinical study. Please let Invicro know if this will not be possible.

6 Participant Safety and Adverse Events

Each participant needs to be monitored for adverse events (AEs) while they are at the imaging center during their imaging visit. Please refer to the main PPMI 2.0 Clinical SPECT and MRI TOMs for details regarding definition and documentation of AEs.

7 Imaging Data Transfer

Imaging data and related documents should be submitted to Invicro within 24 hours. Queries should be resolved within 5 business days of receipt. For further details and instructions regarding image and documentation transfer, receipt notification and data query resolution, please reference the main PPMI 2.0 Clinical SPECT and MRI TOMs.

8 QC & Calibrations

QC measures are to be performed according to the center and scanner manufacturer standard procedures as implemented in the center's QC program for the PET scanner and dose calibrator. All clocks should be synchronized to the PET camera clock.

8.1 Dedicated PET-only Systems

The scanner should have up-to-date 3D well-counter and 3D normalization calibrations on the date of each imaging session. Invicro recommends calibrations be completed on a schedule based on manufacturer's recommendations and requirements. In addition, a daily QC/blank scan (empty port transmission) scan should be done at the beginning of the day the scanning is to be completed. The QC sinogram should be visually inspected for abnormalities. If there is a possibility that the abnormality could impact the quality of the PET scan the scanning visit should be rescheduled. Verification that the daily QC scan has been performed is documented on the web submission form.

8.2 Combined PET/CT Systems

The scanner should have up-to-date 3D well-counter and 3D normalization calibrations on the date of the imaging session as per scanner manufacturer's recommendations. The calibration schedule will be documented and assessed at the time of the site setup. A daily QC check should be done at the beginning of the day the scanning is to be completed. This scan should be visually inspected for abnormalities. If there is a possibility that the abnormality could impact the quality of the PET scan the scan should be rescheduled. Daily CT QC should be performed as recommended by the scanner vendor, but typically should include a "checkup/calibration" procedure and a water phantom scan. The checkup/calibration procedure guarantees optimum image quality by warming up the x-ray tube and should be performed at startup and within 1 hour prior to any scan. The water phantom provides quality measurements of 3 parameters, including the CT value of water calculated in Hounsfield units (HU), the pixel noise of images calculated as a standard deviation, and the tube voltages measured directly on the x-ray tubes. These three measurements should be determined for all intended kVp values.

8.3 Dose Calibrator

QC of the dose calibrator should be performed throughout the course of the study. This typically will include daily constancy, quarterly linearity and annual accuracy tests.

9 PET Scanner Replacement or Upgrades

If your center will be replacing or upgrading your PET scanner or acquisition software, it is critical that you inform Invicro prior to the replacement or upgrade occurring, so that Invicro can take the necessary steps to ensure the continuity of the imaging outcome measures in this longitudinal research study. Invicro may need to revisit the imaging center to acquire another phantom.

10 Supporting Information

10.1 Invicro Contacts

For all questions related to iPACS image data transfer or account credential issues:

corelab_support@invicro.com

For all technical questions related to PET protocol setup or image QC:

Andrea Perez
Sr. Manager II, Imaging QC & Processing
+1-203-401-4315 voice
aperez@invicro.com

For all other study related questions:

Andrew Serrano
Project Manager I
+1-203-990-1638 voice
+1-203-789-8037
aserrano@invicro.com

Nichole Daegele
Director, Project Management
+1-203-401-4367 voice
+1-203-789-8037 fax
ndaegele@invicro.com

For dose ordering and supply inquiries:

For placing [^{18}F] AV-133 dose order:
1 (860) 960-0800 (fax)
clinicalsupply@invicro.com

***For questions related to* [^{18}F] AV-133 dose supply:**
1 (203) 508-1521
clinicalsupply@invicro.com

If shipping images on CD/DVD, you must use the **Invicro Fed Ex # 2295-4740-2** and **add the study Global ID #6892 as the Reference** on the shipping bill.

10.2 TOM Amendment History

This document will be considered draft until final form and a signature page is signed and dated by representatives of the trial Sponsor and by Invicro. Subsequent changes to the final TOM resulting from protocol amendments, and analysis plan or methodology changes will be documented in this section. The TOM will only be updated if there are substantial updates to the clinical protocol or scope of work that alter the imaging details provided in this document.

Version Number	Version Date	Reason for Changes
Final 1.0	04-Apr-2019	Original
Final 2.0	23-Aug-2019	• Updates made to dose ordering and contact information.
Final 3.0	20-Aug-2020	• Updated to align with protocol 004 amendment v2.0, dated 19-Jun-2020 • Updated signatories to align with study oversight • Added Dosing Guide information (Section 4) • Updated contacts information (Section 10) • Added abbreviations table (Section 10) • Removed Scanner Quality Assurance Event Log (Appendix 1) • Added Imaging Parameter Specifications (Appendix 1) • Added [^{18}F] AV-133 Release Form / Dosing Guide example (Appendix 2) • Updated PET submission form example (Appendix 3) • Updated Invicro branding (global) • Editorial changes (global)

10.3 Abbreviations

^{18}F	Fluorine-18
AE	Adverse event
CT	Computed tomography
CTAC	Computed tomography attenuation correction
FOV	Field of view
iPACS	Invicro's data management system
IV	Intravenous
kVp	Peak kilovoltage
MBq	MegaBecquerel
mCi	MilliCurie
PD	Parkinson's Disease
PET	Positron emission tomography
PPMI	Parkinson's Progression Markers Initiative
QA	Quality assurance
QC	Quality control
RSGD	Radiopharmaceutical Supply Guidance Document
TOM	Technical Operations Manual

11 Appendices

11.1 Appendix 1: Imaging Parameter Specifications

An attenuation correction transmission scan needs to be acquired prior to or immediately following the emission scan. For PET-only scanners, an isotope scan may be acquired using a radioactive rod source for approximately 5 to 7 minutes. For PET/CT scanners, a standard low dose CT scan may be acquired. A typical low dose CTAC scan will have an effective mAs of 30 and a tube voltage of approximately 120 kVp.

All PET emission scans will be acquired using one of the following 3D acquisition modes:

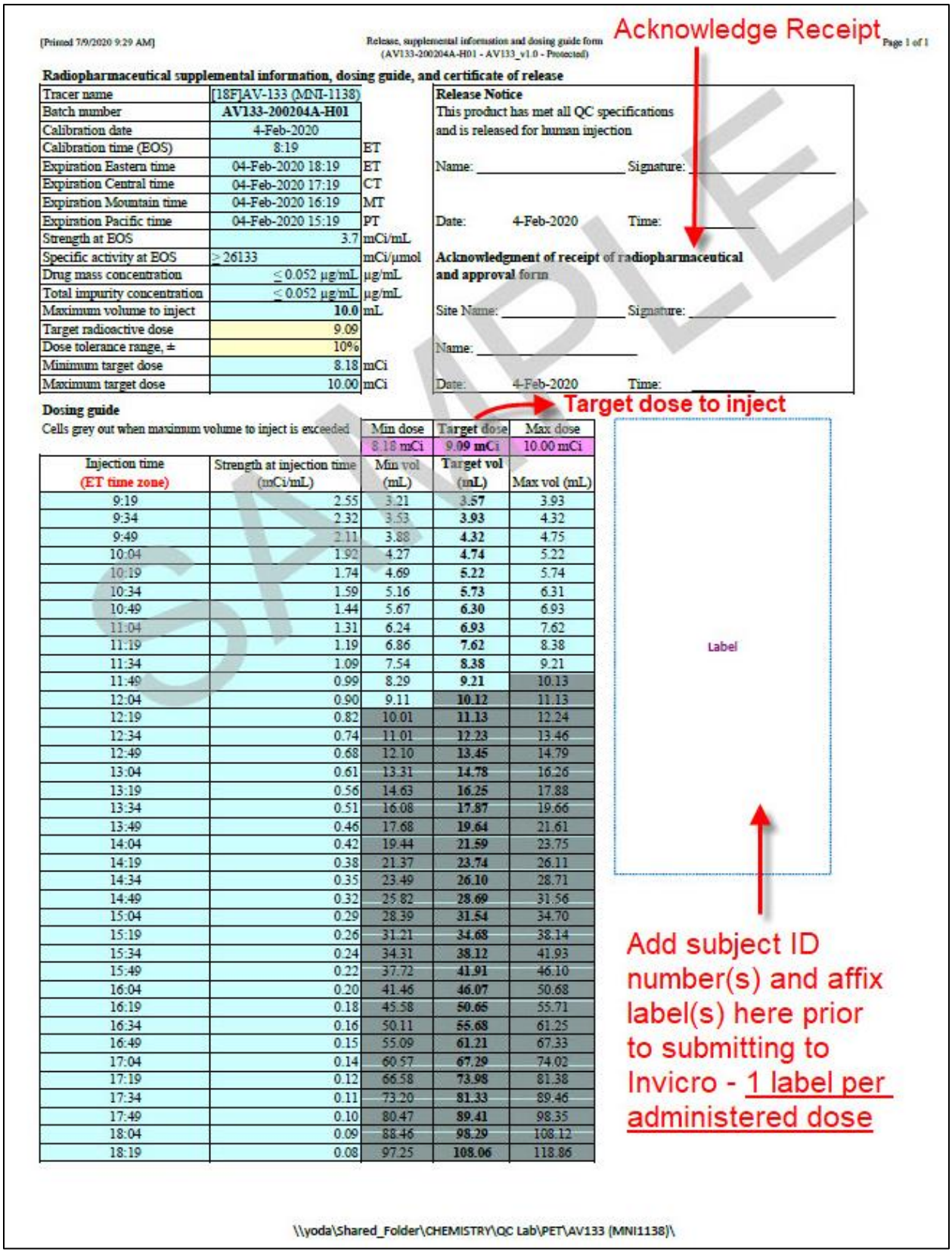
- **List Mode**—allows recording of every detected event (prompts, randoms and the line of response) The acquired list mode data will be subsequently binned and reconstructed into dynamic frames.
- **Dynamic Mode**—data collected in multiple frames of sinograms, each having a predetermined time duration. To allow a dynamic scanning configuration, groups of dynamic scans, each with prescribed number of frames and frame durations to be reconstructed.
- **Sequential Statics**—data collected by acquiring multiple sequential static frames with or without a manual start between each. A prescribed number of static images will be acquired, each with a predetermined duration.

PET images will be corrected for attenuation, random coincidences, scatter & decay, and reconstructed using an iterative reconstruction algorithm that allows for harmonization of data across varying PET scanners. Reconstructed images need to be in quantitative pixel values such as Bq/ml, kBq/cc, etc. and submitted without post filtering applied. Reconstruction parameters will have some variations depending on scanner manufacturer and software version. All parameters will be reviewed and approved by Invicro as part of site qualification and documented in the technical site setup report.

Sites with Philips PET scanners will submit imaging data reconstructed with standard algorithms and parameters applied as documented in the technical site setup report. For Philips scanners; iterations and subsets should be documented as “Standard” during image data submission.

Example of Typical PET Emission Acquisition(s)	
PET Imaging Mode:	3D (septa-retracted)
Acquisition Type:	List Mode, Dynamic, or Sequential Statics
Reconstruction Method:	• Iterative • Number of iterations, subsets and image matrix will vary based on scanner and software version and will be determined during site qualification
Corrections:	Scatter, Decay, Randoms
Attenuation Correction:	Measured (CTAC or Transmission)
Zoom:	2 (or DFOV 25.6 cm)
Un-filtered Reconstruction:	Filter parameter set to "*None*","*0.0*", and/or "*All Pass*"
Slice Thickness:	• 2-4 mm • Default slice thickness must be used for all scanner models "*Match CT Slice Location*" must be unselected (ie, turned off) for all Siemens Biograph PET scanners with this reconstruction option

11.2 Appendix 2: [18F]AV-133 Release Form / Dosing Guide (Example)



[Printed 7/9/2020 9:29 AM]

Release, supplemental information and dosing guide form
(AV133-200204A-H01 - AV133_v1.0 - Protected)

Page 1 of 1

Acknowledge Receipt

Radiopharmaceutical supplemental information, dosing guide, and certificate of release

Tracer name	[18F]AV-133 (MNI-1138)	
Batch number	**AV133-200204A-H01**	
Calibration date	4-Feb-2020	
Calibration time (EOS)	8:19	ET
Expiration Eastern time	04-Feb-2020 18:19	ET
Expiration Central time	04-Feb-2020 17:19	CT
Expiration Mountain time	04-Feb-2020 16:19	MT
Expiration Pacific time	04-Feb-2020 15:19	PT
Strength at EOS	3.7	mCi/mL
Specific activity at EOS	≥ 26133	mCi/µmol
Drug mass concentration	≤ 0.052 µg/mL	µg/mL
Total impurity concentration	≤ 0.052 µg/mL	µg/mL
Maximum volume to inject	**10.0**	mL
Target radioactive dose	9.09	
Dose tolerance range, ±	10%	
Minimum target dose	8.18	mCi
Maximum target dose	10.00	mCi

Release Notice
This product has met all QC specifications and is released for human injection

Name: _____ Signature: _____

Date: 4-Feb-2020 Time: _____

Acknowledgment of receipt of radiopharmaceutical and approval form

Site Name: _____ Signature: _____

Name: _____

Date: 4-Feb-2020 Time: _____

Target dose to inject

Dosing guide

Cells grey out when maximum volume to inject is exceeded

Injection time (ET time zone)	Strength at injection time (mCi/mL)	Min dose 8.18 mCi: Min vol (mL)	Target dose 9.09 mCi: Target vol (mL)	Max dose 10.00 mCi: Max vol (mL)
9:19	2.55	3.21	**3.57**	3.93
9:34	2.32	3.53	**3.93**	4.32
9:49	2.11	3.88	**4.32**	4.75
10:04	1.92	4.27	**4.74**	5.22
10:19	1.74	4.69	**5.22**	5.74
10:34	1.59	5.16	**5.73**	6.31
10:49	1.44	5.67	**6.30**	6.93
11:04	1.31	6.24	**6.93**	7.62
11:19	1.19	6.86	**7.62**	8.38
11:34	1.09	7.54	**8.38**	9.21
11:49	0.99	8.29	**9.21**	10.13
12:04	0.90	9.11	**10.12**	11.13
12:19	0.82	10.01	**11.13**	12.24
12:34	0.74	11.01	**12.23**	13.46
12:49	0.68	12.10	**13.45**	14.79
13:04	0.61	13.31	**14.78**	16.26
13:19	0.56	14.63	**16.25**	17.88
13:34	0.51	16.08	**17.87**	19.66
13:49	0.46	17.68	**19.64**	21.61
14:04	0.42	19.44	**21.59**	23.75
14:19	0.38	21.37	**23.74**	26.11
14:34	0.35	23.49	**26.10**	28.71
14:49	0.32	25.82	**28.69**	31.56
15:04	0.29	28.39	**31.54**	34.70
15:19	0.26	31.21	**34.68**	38.14
15:34	0.24	34.31	**38.12**	41.93
15:49	0.22	37.72	**41.91**	46.10
16:04	0.20	41.46	**46.07**	50.68
16:19	0.18	45.58	**50.65**	55.71
16:34	0.16	50.11	**55.68**	61.25
16:49	0.15	55.09	**61.21**	67.33
17:04	0.14	60.57	**67.29**	74.02
17:19	0.12	66.58	**73.98**	81.38
17:34	0.11	73.20	**81.33**	89.46
17:49	0.10	80.47	**89.41**	98.35
18:04	0.09	88.46	**98.29**	108.12
18:19	0.08	97.25	**108.06**	118.86

Label

Add subject ID number(s) and affix label(s) here prior to submitting to Invicro - 1 label per administered dose

\\yoda\Shared_Folder\CHEMISTRY\QC Lab\PET\AV133 (MNI1138)\

SAMPLE

11.3 Appendix 3: Submission Form (Example)

PPMI 2.0 Protocol Number 004

Invicro
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Early Imaging AV-133 Submission Form

Clinical Site ID: ☐☐☐

Subject Number (Participant ID): ☐☐☐☐ (4-digit 1.0 transition subjects)
☐☐☐☐☐ (5-digit 1.0 transition subjects)
☐☐☐☐☐☐ (6-digit 2.0 new subjects)

Scan Acquisition Date (DD-MMM-YYYY): ☐☐ - ☐☐☐ - ☐☐☐☐

Modality: ☐ PET

Cohort: ☐ PD

Radiopharmaceutical: ☐ 18F-AV-133

PET Imaging Timepoint:
☐ Baseline (Day 0)
☐ Month 6/V02
☐ Month 12/V04
☐ Month 18/V05

Batch Number: ☐☐☐☐☐☐☐☐☐☐

F-18-AV-133 Passed QC:
☐ Yes
☐ No

Expiration Date (DD-MMM-YYYY): ☐☐ - ☐☐☐ - ☐☐☐☐

Expiration Time (HH:MM; 24hr): ☐☐:☐☐

Weight: ☐☐☐.☐☐ ☐ lb ☐ kg

Injection Site: ☐☐☐☐☐☐☐☐☐☐

Volume of Injection: ☐☐☐.☐☐ ☐ ml

Initial Activity in Syringe: ☐☐☐.☐☐ ☐ mCi ☐ MBq

Initial Activity Time Measured (HH:MM; 24hr): ☐☐:☐☐

Date of Injection (DD-MMM-YYYY): ☐☐ - ☐☐☐ - ☐☐☐☐

Time of Injection (HH:MM; 24hr): ☐☐:☐☐

Residual Activity Post Injection: ☐☐☐.☐☐ ☐ mCi ☐ MBq

Residual Activity Time Measured (HH:MM; 24hr): ☐☐:☐☐

CONFIDENTIAL
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PPMI 2.0_AV-133_V1.0_21JUL2020