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The EPSMS Pathway: Immuno-Neuro-PET with Theranostics as a Research Framework to Find a Cure for Multiple Sclerosis*

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Abstract

The EPSMS Pathway envisions immuno-neuro-PET with theranostics as a research framework to find a cure for multiple sclerosis. Brain Health Alliance will continue development for this pathway with a research agenda over the next 10 years to build web-enabled platform support, de-identified image data repositories, knowledge engineering, and international collaboration on sequential phases of a multi-site clinical trial for PET medical imaging with an emphasis on standardization and harmonization across multiple sites. This report currently focuses on the initial exploratory phase for the next 3 years, known as the EPSMS Clinical Trial with Entire-body PET Scans for Multiple Sclerosis, as a multi-site clinical trial that is already in progress. The present phase of EPSMS aims to (1) assess the differences in uptake of FDA-approved amyloid imaging radiotracers in normal, demyelinated, and remyelinated white matter in the nervous system between MS patients and healthy subjects, and (2) explore the psychological effects on participants when informed about their imaging results. Future phases of the EPSMS Pathway will investigate the use of PET imaging radiotracers for immune system biomarkers and the potential of theranostics to ameliorate the dysregulation of the immune system that occurs in multiple sclerosis as an auto-immune disorder. Thus, the importance of entire-body medical imaging remains paramount in order to visualize the immune system and monitor biomarkers in the bone marrow, thymus, spleen, lymph nodes and lymphatic system.

Keyphrases

Multiple sclerosis, auto-immune disorders, neurodegenerative disorders, entire-body PET scans, immuno-neuro-PET, theranostics, EPSMS.

Contents

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Background

The EPSMS Clinical Trial investigates use of state-of-the-art high-resolution entire-body positron emission tomography (PET) scans (with acronym EPS from the phrase *Entire-body PET Scans*) for functional molecular imaging of the nervous system to evaluate both peripheral and central demyelination and remyelination in multiple sclerosis (MS). This study hypothesizes that the improved sensitivity and resolution of advanced PET scanners can detect demyelination not only in the brain and spinal cord but also in peripheral nerves, an approach that has not been fully explored in past conventional imaging for MS with magnetic resonance imaging (MRI). The study employs FDA-approved PET amyloid imaging radiopharmaceuticals (F18-florbetapir, F18-florbetaben, and F18-flutemetamol) which also bind to myelin, enabling the assessment of demyelination and remyelination dynamics. Related radiotracers have shown promise (see Table 1 for differential grey-white matter binding, Figure 1 for normal subject, and Figure 2 for MS patients) in prior studies demonstrating quantifiable changes in myelin content and remyelination potential (Stankoff et al. 2006; Stankoff et al. 2011; Glodzik et al. 2014; Veronese et al. 2015; Matias-Guiu et al. 2015; Bodini et al. 2016; Pietroboni et al. 2018; Bodini et al. 2021).

Table 1: Signal versus Noise for Amyloid Imaging Agents

	Target Signal	Off-target Noise
Alzheimer's Disease	grey matter	white matter
Multiple Sclerosis	white matter	grey matter

Entire-body PET scans not only enable functional molecular imaging with neuro-PET of both central and peripheral nervous system to include brain, spinal cord and peripheral nerve roots, but also enable molecular imaging with immuno-PET (see Figure 3) of the immune system in bone marrow, spleen, thymus, and lymph nodes (Wei et al. 2020; Gao et al. 2022; Wu et al. 2022; Lucas et al. 2023; Mohr et al. 2024).

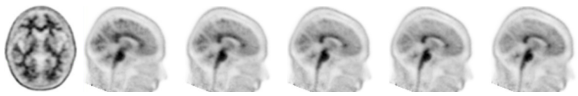

Figure 1: High binding of F18-flutemetamol in white matter with low binding in gray matter; images courtesy of Chris Rowe, University Melbourne, Australia.

Dual-tracer PET scans will enable molecular imaging of both immune and nervous systems with immuno-neuro-PET for MS. Theranostics with the use of dual-purpose radiotracers for both diagnostic imaging and therapeutic interventions will provide a pathway that supports a research framework to find a cure for MS.

Preliminary Results

The EPSMS Study NCT04390009 was initially registered at ClinicalTrials.gov in 2020 with the protocol published in 2020 and amended in 2023 (Taswell 2020; Taswell 2023), but was then delayed with a hold on start of the trial due to the COVID19 pandemic. The clinical trial protocol emphasizes standardization of PET molecular imaging at multiple imaging sites to ensure consistent data acquisition across different scanners. A report on the EPSMS Study as a clinical trial in progress was presented at the SNMMI 2025 Annual Meeting (Taswell, Jordan, et al. 2025) and (at the time of writing) a total of 7 Amyvid PET scans have now been completed including several study partner pairs from the same families (ie, a mother-daughter pair and a sister-brother pair) with one partner in the pair an MS patient and the other participating as a normal subject. Amyvid (F18-florbetapir, Eli Lilly and Company (2025)) for PET molecular imaging scans (Taswell 2020, p.6) is not available for use in some countries and at some potential collaborating medical imaging centers. Therefore, the EPSMS Study protocol was amended again in 2025 (Taswell 2025) to include other FDA-approved amyloid imaging agents. Neuraceq (F18-florbetaben, Life Molecular Imaging Ltd (2025)) and Vizamyl (F18-flutemetamol, (GE Healthcare Inc 2025)) will now also be used according to the expertise of the imaging center and availability of the radiopharmaceutical at the location. If PET scans with amyloid imaging biomarkers prove successful monitoring myelin lesions, the findings could support better patient care decisions, improve clinical trial outcome measures, and advance therapeutic evaluations for MS. This study represents a pioneering effort to apply entire-body PET functional molecular imaging for comprehensive monitoring of MS pathology for the entire nervous system.

Experimental Design and Methods

The experimental paradigm involves an approach similar to that demonstrated for amyloid imaging tracers used for Alzheimer's disease and related disorders with safety of imaging results disclosure monitored with pre- and post-scan psychometrics (Taswell, Villemagne, et al. 2015; Taswell, Donohue, et al. 2018). Exposition of the formal clinical trial protocol with complete details of the experimental design and methods was published in "Research Protocol for Exploratory Study of Entire-body PET Scans for Multiple Sclerosis (EPSMS)" by Taswell (2020) then amended by Taswell (2023) and Taswell (2025).

The current phase of the EPSMS Pathway uses advanced PET imaging to analyze the activity of myelin-binding radiopharmaceuticals in the nervous systems of patients with MS. This *study aims (1) to assess the differences in uptake of FDA-approved amyloid imaging radiotracers in normal, demyelinated, and remyelinated white matter between MS patients and healthy controls, and (2) to explore the psychological effects on participants when informed about their imaging results.* Participants undergo PET scans with recent state-of-the-art high-resolution PET scanners (cf, Zhang et al. 2024) at partner imaging sites.

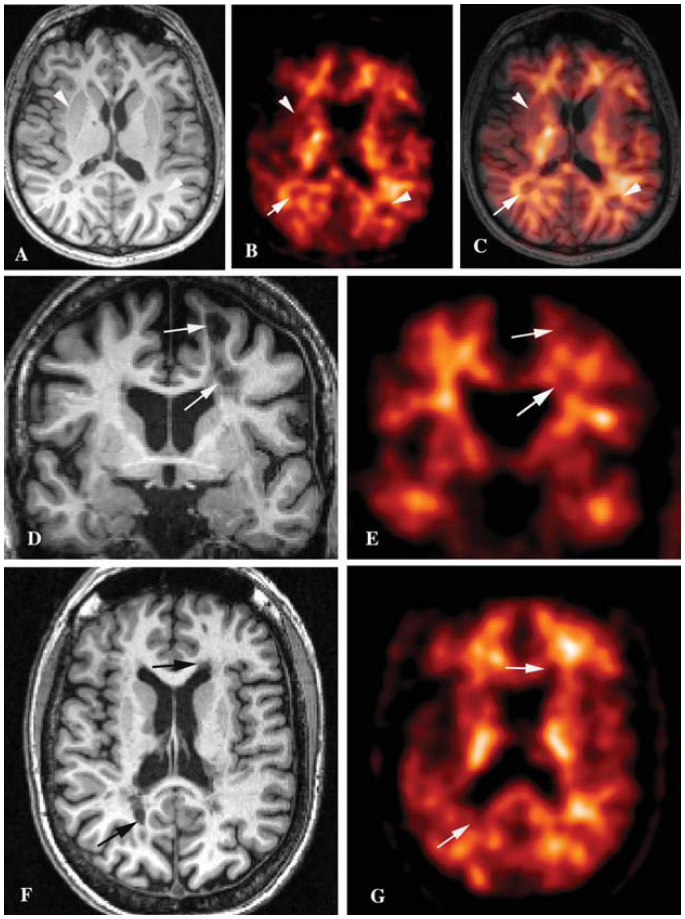

Figure 2: MP-RAGE 3T MRI and C11-PiB PET images for MS patient 1 (A-C) and MS patient 2 (D-G); reprinted from Stankoff et al. (2011).

A total of 40 participants (30 MS patients and 10 normal controls) will participate in the exploratory phase of this study with 20 Amyvid doses already allocated with in-kind support from Avid Radiopharmaceuticals and 20 Neuraceq doses pending approval with in-kind support from Life Molecular Imaging. *Specific assessments include MS-related disability, psychological health (pre- and post-scan), and myelin-related changes in the brain, spinal cord, and peripheral nerve roots as visualized in the PET scans.* Eligibility includes adults age 25–65 as control subjects with normal health or as MS patients diagnosed by credentialed neurologists with MS experience, and excludes individuals with complicating illnesses, recent medical procedures, or contraindications to medical imaging.

PET scan images are analyzed to measure relative tracer activity levels in key regions, correlating these results with clinical symptoms, psychometrics, and MS-related lesions observed in other imaging modalities, notably MRI, when available from patients' medical records. PET scan images obtained from partner imaging sites that support multimodal imaging on back-to-back PET-CT and PET-MR scanners within the same session using the same single dose of administered radiotracer are analyzed further to evaluate multimodal correlation between

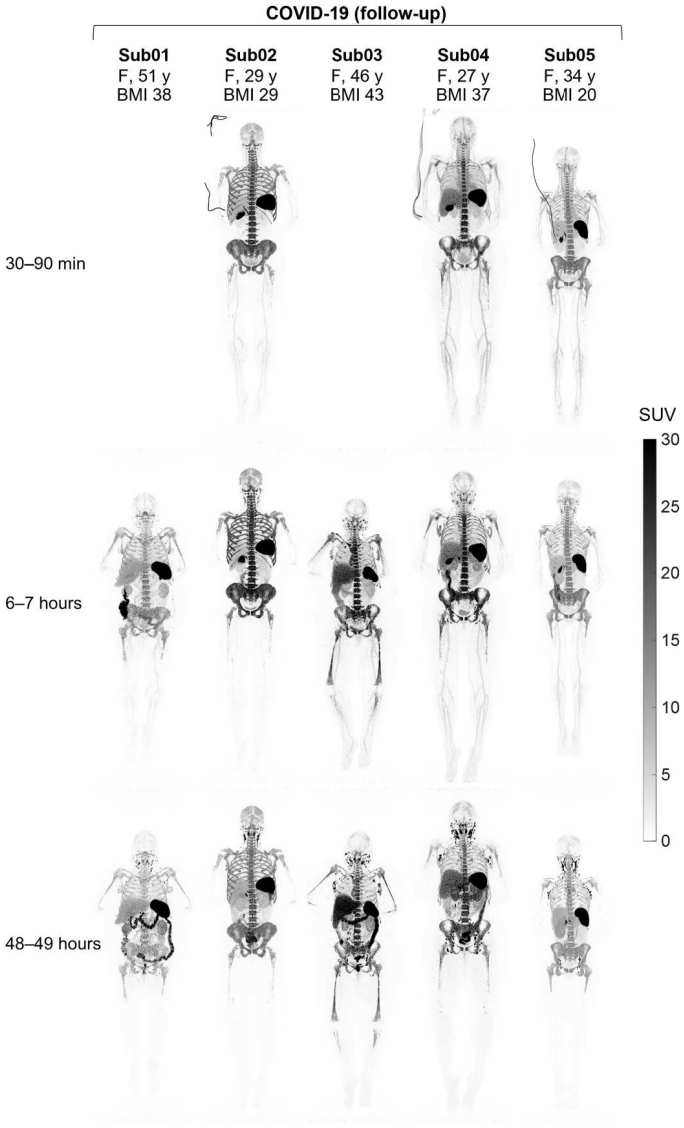

Figure 3: Dynamic immuno-PET imaging of COVID19 convalescent patients with CD8-targeted minibody; reprinted from Omidvari et al. (2023).

images obtained for participants with both PET-CT and PET-MR modalities. This approach enables standardization for multimodal image data acquisition while minimizing participant burden and radiation exposure. PET scan images obtained in this manner facilitate correlation between PET molecular imaging for functional metrics with MRI anatomic imaging for structural metrics.

Findings expected include (1) differences in radiotracer activity between MS patients and healthy controls, (2) identification of topographic variations in activity across regions of the central and peripheral nervous systems, and (3) an initial data repository with web-enabled workflow infrastructure to support future studies on the role of PET imaging for MS diagnostics, monitoring of disease modifying therapies, and future theranostics. *All participants must consent to the study and can opt in/out of imaging results disclosure for neither, either, or both of gray and white matter results.* Radiation exposure levels are minimal and within safety standards for the FDA-approved radiopharmaceuticals used. Potential risks include adverse reactions to the tracer, discomfort during imaging, and the possibility of unrelated incidental findings. *The website EPSMS.brainhealthalliance.net serves as the online management service for the EPSMS Study.*

Future phases of the EPSMS Clinical Trial will involve novel radiotracers to evaluate neuroinflammation and biomarkers of immune system activity. *This study represents a pioneering effort to apply entire-body PET functional molecular imaging from top-of-head to bottom-of-pelvis for comprehensive monitoring of MS pathology in the nervous system and immune system with immuno-neuro-PET.*

Pathways-to-Cures Roadmap Relevance

In recent years, there has been some debate about different definitions, interpretations and usage for the terms *theranostics*, *theragnostics*, and *iamagnostics* (Wiesing 2019; Retsas 2024). This report on the EPSMS Pathway for theranostics as a research framework adheres to the usage discussed by Currie (2024) consistent with the history and clinical practice of nuclear medicine and molecular imaging. In simplest terms, *theranostics* is interpreted here as the use of PET molecular imaging with radiopharmaceuticals that can be used for both diagnostic and therapeutic purposes. The NMSS Pathways-to-Cures Roadmap (Bebo, Allegretta, et al. 2022; Bebo, Banwell, et al. 2024; Cobo-Calvo and Tintore 2024) describes three different pathways called *Stop* (worsening progression), *Restore* (lost function), and *End* (by prevention). Because advances in PET imaging with myelin-binding radiotracers can support monitoring of demyelination and remyelination in MS (Oh et al. 2019; Lubetzki et al. 2020), the EPSMS framework can be applied to the Stop and Restore Pathways. As soon as radiotracers are developed to serve as disease-modifying interventions to ameliorate the dysregulation of the immune system and its interaction with the nervous system (Di Filippo, Portaccio, et al. 2018), PET theranostics can be applied to the Stop and Restore pathways, especially for high-risk individuals as determined by genetic (Neidich 2023) and fluid (Di Filippo, Gaetani, et al. 2024) biomarkers evaluated with risk assessments (Peeters et al. 2025) for precision medicine (Chitnis and Prat 2020). If these radiotracers prove to be sensitive enough to detect changes in the immune system early enough in the pathophysiological mechanisms of the auto-immune disorder, then PET theranostics can also be used for the End pathway. Thus, the EPSMS Pathway with immuno-neuro-PET theranostics as a research framework can potentially serve all three of the NMSS Pathways *Stop*, *Restore*, and *End* to find a cure for MS.

Facilities Available

Current partner imaging sites for the EPSMS Clinical Trial include the Northern California PET Imaging Center (NCPIC) in Sacramento, CA, directed by Dr. Dafang Wu, and the Center for Molecular Imaging and Therapy (CMIT) in Shreveport, LA, directed by Dr. Stephen Lokitz. Several PET scans have already been completed at each of NCPIC and CMIT. Additional sites with nuclear medicine and molecular imaging services at BAMF Health (BAMF) in Grand Rapids, MI, directed by Dr. Harshad Kulkarni, University Hospitals (UH) in Cleveland, OH, directed by Dr. David Jordan, and Lausanne University Hospital (CHUV) in Lausanne, Switzerland, directed by Dr. John Prior, have agreed to collaborate on the EPSMS Clinical Trial.

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