

## BACKGROUND

Multiple sclerosis (MS) is a chronic inflammatory and neurodegenerative disorder marked by unpredictable neurologic fluctuations and subtle gait changes that may precede clinical deterioration.

### Epidemiology of Multiple Sclerosis

- Approximately 1 million individuals are diagnosed in the United States
- Most commonly diagnosed between 20 and 40 years of age
- Disproportionately affects women (3:1 ratio)
- Occurs across all racial and ethnic groups, with differences in incidence, severity, and outcomes
  - Reported more frequently in White ancestry; however, emerging data show substantial disease burden in Black patients
- About 85% of patients initially present with relapsing-remitting disease, and most transition to secondary progressive MS
  - Secondary progressive MS is driven by neurodegeneration despite treatment with disease-modifying therapies (DMTs)

Pharmacists play an established role in MS care through adherence assessment, adverse-event monitoring, counseling, and coordination under collaborative practice agreements, yet they lack structured tools to detect silent functional decline.

## OBJECTIVES

### Primary Objective

- Evaluate the feasibility, safety, and technical performance of the StepForwardRx mobile application and dashboard in capturing longitudinal gait metrics.

### Secondary Objectives

- Assess usability and acceptability of the CDSS among participants.
- Evaluate workflow integration and interdisciplinary utility within pharmacist–neurologist collaborative practice models.
- Characterize baseline gait variability and refine individualized deviation thresholds prior to MS deployment.

## ACKNOWLEDGMENTS

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## METHODS

### System Architecture & Workflow Design

- Synthesizes walking speed, step length, step time, double support time, and gait asymmetry.
- Compares patient-level trends to individualized baselines.
- Generates internal risk-tiered prioritization categories (low, moderate, high).
- Preserves clinician interpretability consistent with FDA Non-Device Clinical Decision Support (CDS) guidance.
- Supports structured pharmacist documentation and interdisciplinary communication.

### Phase 0 Baseline Study (Healthy Volunteers)

#### Design:

- Prospective, single-site, observational study
- 10 healthy adult volunteers
- 14-day data collection period

#### Endpoints:

- ≥80% successful gait metric capture
- Baseline distribution of five gait variables
- Variability within expected physiologic ranges
- Absence of serious adverse events related to app usage
- System Usability Scale (SUS) score ≥ 70

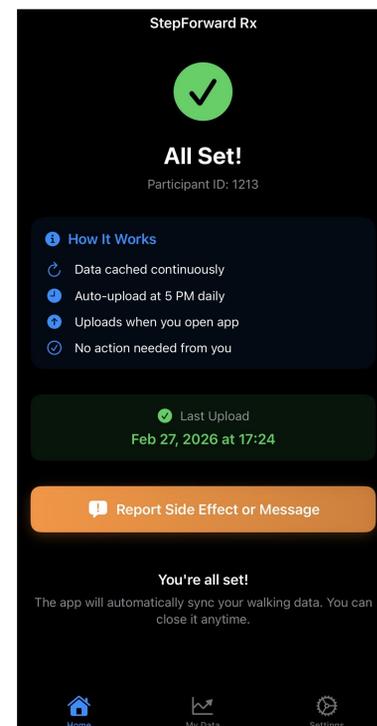


FIGURE 1. PATIENT PHONE INTERFACE

### Phase 1 Pilot Study (MS Subpopulation)

#### Design:

- Prospective observational pilot
- Specialty pharmacy setting in partnership with neurology practices under CPAs
- Patients with relapsing-remitting MS initiating or escalating DMT

#### Primary Outcomes:

- Workflow efficiency (time from risk signal to intervention)
- Agreement between generated prioritization categories and pharmacist clinical assessment
- Assessment of pharmacist–neurologist collaboration dynamics

#### Secondary Outcomes:

- System usability, interpretability, and perceived workflow burden

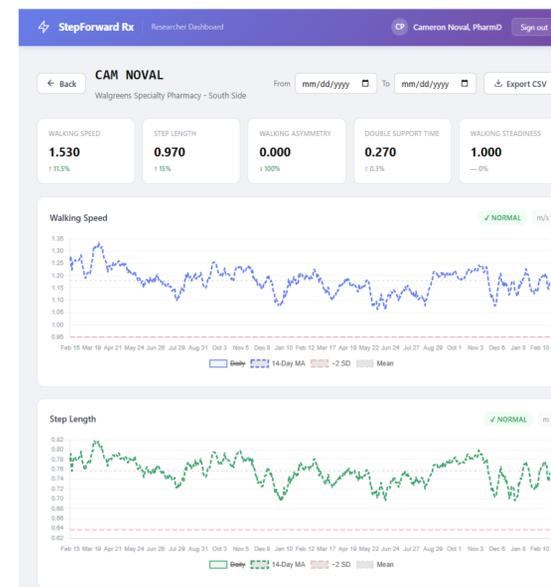


FIGURE 2. SAMPLE PROVIDER WEBSITE INTERFACE

## PRELIMINARY RESULTS

StepForwardRx has completed iterative prototype development using simulated gait datasets and TestFlight beta deployment.

### Current platform capabilities include

- Successful integration of Apple Health gait metrics from patient to individual and collective pharmacy-specific dashboards
- Real-time visualization of longitudinal variability trends
- Integration of patient medication timelines with biometric data
- Flag patients with irregular 14-day moving-average metrics (beyond 2 SD)
- Secure HIPAA-compliant infrastructure

### Preliminary simulation testing demonstrates

- Clear differentiation of variability patterns across gait metrics
- The importance of individualized baseline modeling
- Feasibility of pharmacist-led review without excessive alert burden

Phase 0 healthy volunteer testing is planned to validate baseline thresholds and confirm system stability prior to Phase 1 deployment.

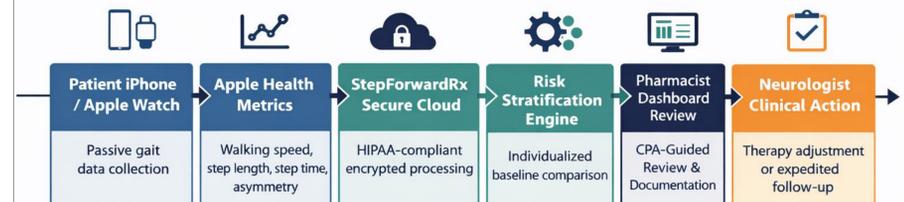


FIGURE 3. STEPFORWARDRX PHARMACIST-LED CLINICAL WORKFLOW

Is designed to enable earlier identification of subtle gait and mobility deviations between clinical encounters, supporting proactive recognition of functional change in neurologic populations.

Supports pharmacist-led risk stratification and therapy assessment under Collaborative Practice Agreements (CPAs), with the goal of facilitating timely intervention and coordinated, team-based care.

Facilitates structured, bidirectional communication between pharmacy and neurology teams through shared longitudinal dashboards and documented clinical workflows.

Provides objective, real-world functional data captured passively via mobile devices, expanding longitudinal insight while integrating into existing clinical workflows to minimize additional burden and alert fatigue.

FIGURE 4. PROJECTED CLINICAL INTEGRATION & IMPACT