

A Novel International Patient Registry in Myasthenia Gravis Linking Clinical and Patient-Reported Outcomes Data: The Vitaccess Real MG (VRMG) Registry

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Objective

To design a global patient registry (“*Vitaccess Real MG*”) to optimally quantify the impacts of disease and treatment on patients living with myasthenia gravis (MG). The Vitaccess Real MG (VRMG) registry links data reported directly by patients with clinical data reported by healthcare professionals (HCPs) and captured from patients’ medical records.

Background

MG is a rare, chronic, autoimmune disease characterized by debilitating and fluctuating muscle weakness¹. There is no robust, existing international resource of real-world data for MG research that combines patient-reported outcomes (PROs) and clinical data. The purpose of the VRMG registry, which is a multi-industry stakeholder initiative, is to facilitate a range of registry-based research studies to further evaluate the real-world impact of MG and its treatment – including the real-world pharmacoepidemiological study of novel therapies.

Design/Methods

VRMG is designed to capture longitudinal observational data on MG and its impact on symptoms, daily activities, and health-related quality of life (HRQoL). At the time of writing, the registry has been launched in the United States (US) and United Kingdom (UK), with expansion to additional European countries planned for 2025/6. Adult patients with a clinically-confirmed diagnosis of generalized or ocular MG will be eligible to participate if they reside in one of the included countries. The data from this registry will support future clinical and epidemiological studies on MG².

Recruitment

In participating countries, recruitment can occur at medical centers, with HCPs contributing clinical data from patients’ medical records. In the US only, patients can also be recruited direct-to-patient or via their treating community neurologist; in both cases, clinical data are captured retrospectively via an electronic medical record (EMR) aggregator.

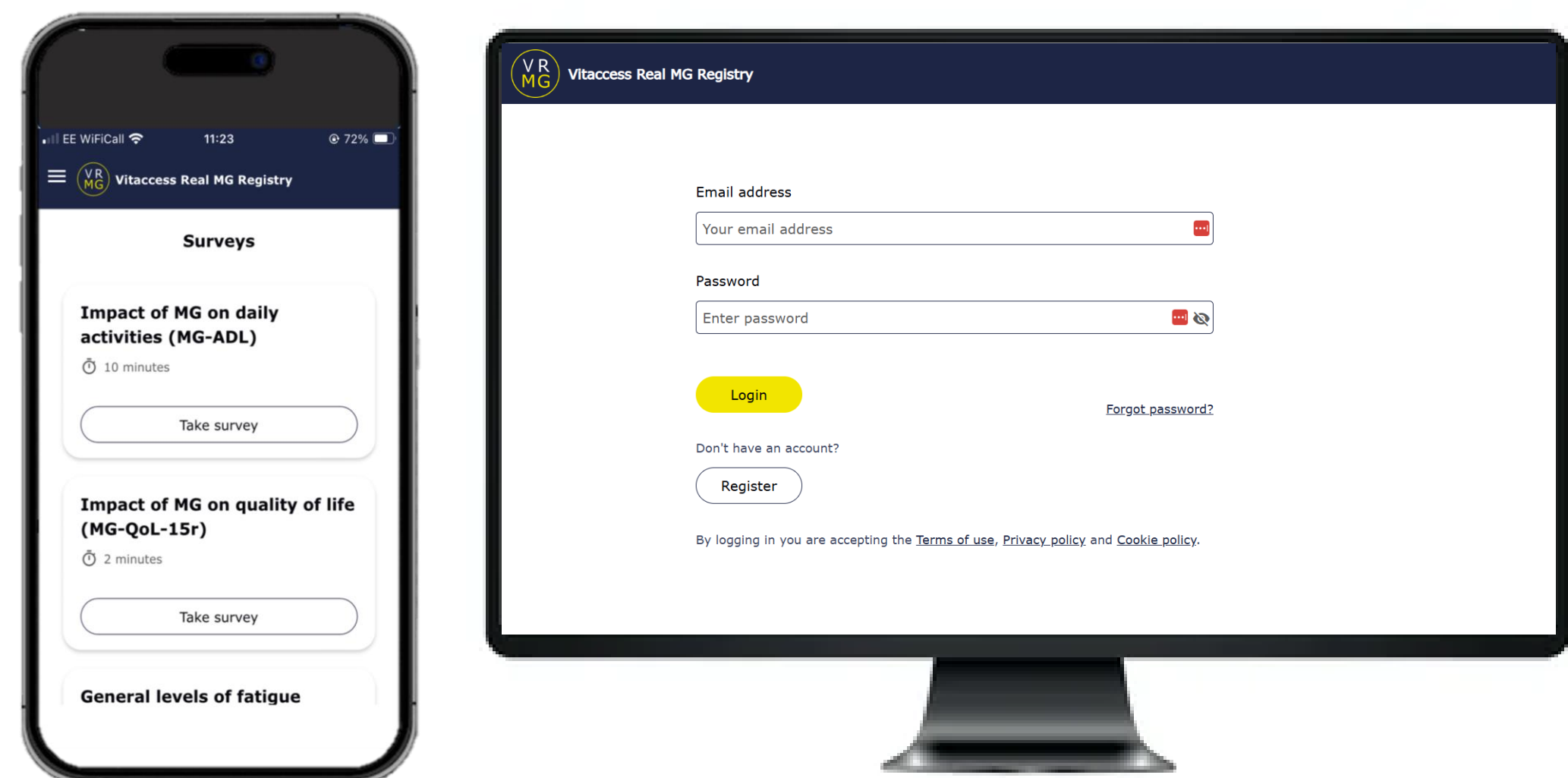


Figure 1 – The Vitaccess Real MG registry platform. Patient participants can access the platform on their own device (smartphone/tablet/desktop/laptop) to complete patient-reported outcome measures on a monthly or bi-monthly basis.

Data capture

Patients contribute PRO data via the VRMG registry platform, which they can access on their own device (smartphone/tablet/computer/laptop) (**Figure 1**). Patients can additionally opt in to receiving weekly short message service (SMS) surveys to capture MG symptom changes. If the participant confirms a symptom change in their SMS response, this will trigger administration of an additional MG-ADL. The platform is deployed alongside a web-based electronic case report form (eCRF) platform for clinical data capture from HCPs and medical records. Clinical data are captured on a six-monthly basis.

Table 1 summarizes the types of data captured in the registry. **Figure 2** illustrates the design of the registry, including the various recruitment channels and data sources.

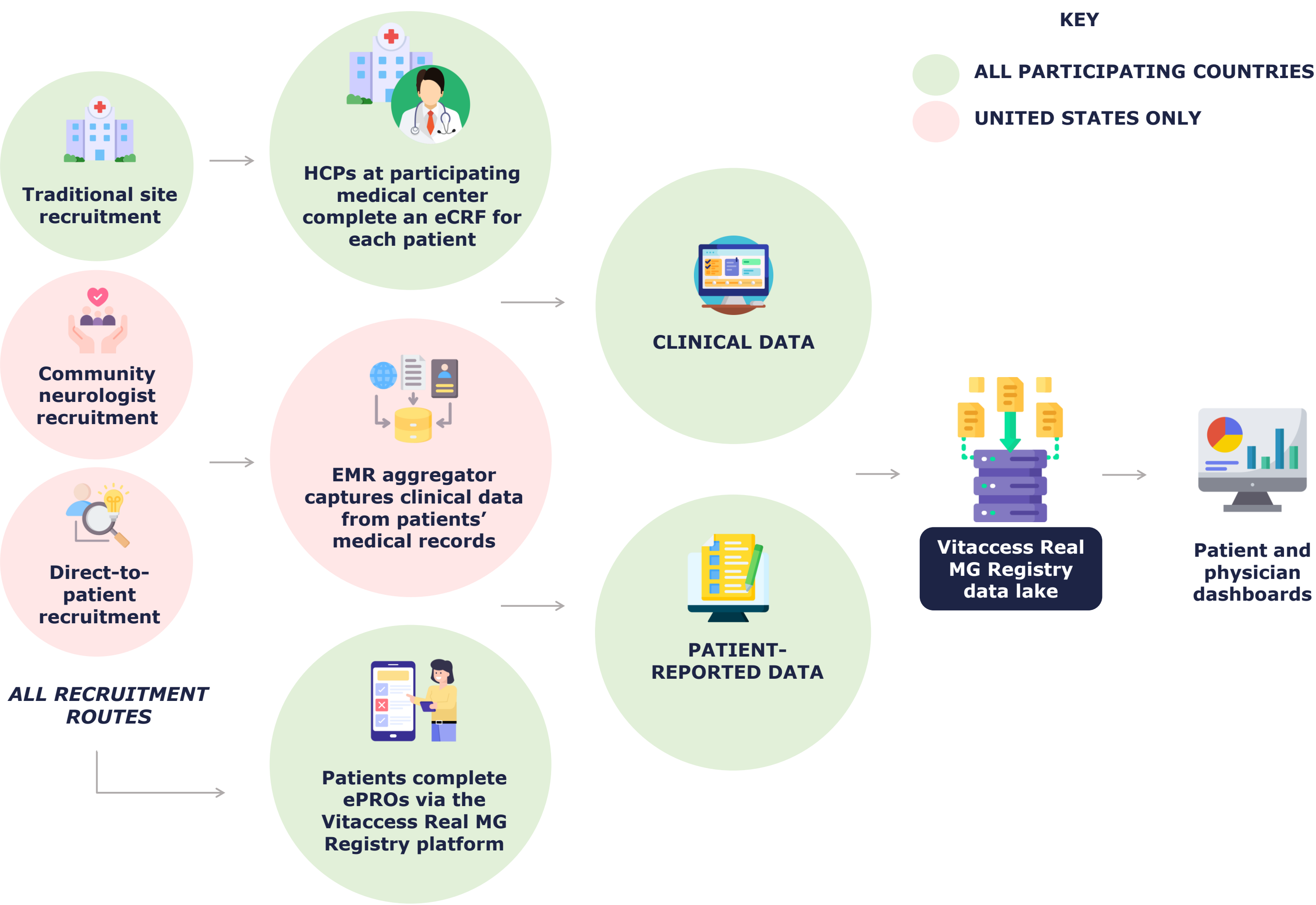


Figure 2 – Design of the Vitaccess Real MG registry, including different participant recruitment approaches and data sources. Patients can be recruited via traditional site, direct-to-patient, or community neurologist recruitment. Clinical data matching predefined eCRF outputs are combined with digitally-captured PRO data to generate the registry data lake. Registry data in turn can be processed and viewed in physician or patient dashboards.

eCRF = Electronic case report form; EMR = Electronic medical record; ePRO = Electronic patient-reported outcome; HCP = Healthcare professional; MG = myasthenia gravis

Patient-reported data	Clinical data
<i>Collected monthly or bi-monthly</i> <ul style="list-style-type: none">• MG-ADL³ (Assesses the impact of MG on daily activities in the past 7 days)• MG Symptoms PRO Fatigue Scale⁴ (Assesses the experience of fatigue in the past 7 days)• Neuro-QOL Fatigue Short Form⁵ (Assesses the experience of fatigue in the past 7 days)• MG-QoL 15r⁶ (Assesses health-related quality of life in the past few weeks).	<i>Collected at baseline and 6-monthly</i> <ul style="list-style-type: none">• Demographic information• Clinical trial participation• Diagnosis information• Clinical characteristics• Medical history• Comorbidities• Treatment history (concomitant, routine, and rescue treatments)• Historical MG-ADL (i.e., MG-ADL scores recorded up to two years pre-baseline)• Interviewer-administered (i.e., reported by an HCP) MG-ADL• Healthcare resource use• Adverse events

Table 1 – Overview of data captured in the Vitaccess Real MG registry, including: (a) patient-reported data captured directly from patients via the Vitaccess Real digital data capture platform; and (b) clinical data captured by HCPs via an eCRF or by an EMR aggregator (depending on the recruitment route of the participant).

HCP = Healthcare professional; MG = myasthenia gravis; MG-ADL = Myasthenia Gravis Activities of Daily Living; MG-QoL-15r = Myasthenia Gravis Quality of Life 15-item Revised Scale

Results

Direct-to-patient and community neurologist recruitment in the US were initiated in August 2024, and site recruitment in the US and UK were initiated in September 2024 and March 2025, respectively. Expansion to additional European countries is planned for 2026.

Conclusions

By integrating digitally-captured clinical and patient-reported data, this novel registry aims to improve understanding of the symptoms and quality of life impact experienced by MG patients, in order to support their disease management

References

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Vitaccess Ltd. is the Sponsor of the Vitaccess Real MG Registry. UCB is the first subscriber of the Vitaccess Real MG Registry and has funded its setup. The registry is maintained by multiple industry subscriptions.

