APPROVED BY SALUS IRB: 08 OCTOBER 2020

AN AGREEMENT TO BE IN A RESEARCH STUDY
INFORMED CONSENT DOCUMENT

Sponsor:	Doc.ai
City and State:	Palo Alto, CA
Protocol Number and Title:	DOC-005-2020 A digital health trial that assesses participant-driven data collection using smartphone modules to characterize myasthenia gravis symptoms and develop an A.I. model to predict flares
Principal Investigator:	Dr. Sandra Steyaert, PhD
Address of Study Site(s):	doc.ai 636 Waverley Street, Suite 200 Palo Alto, CA 94301
24-Hour Contact:	(650) 382-4268
Email Contact:	mgstudy@doc.ai

PURPOSE OF RESEARCH

You are being invited to participate in the doc.ai data research study because you have Myasthenia Gravis (MG). Myasthenia Gravis (MG) is a chronic neurological disorder that causes weakness in different muscle groups and affects more than a million people worldwide. We are trying to develop an artificial intelligence (AI) model to see if there is an effective way to find patterns and reasons why symptoms flare up. doc.ai, is a Silicon Valley artificial intelligence company whose advanced technologies make it possible for anyone with a smartphone to participate in this research.

Funding for this study has been provided by UCB Biopharma (SRL).

With the information you provide we want to learn if we can develop a way for people to understand the pattern of their MG symptoms so that they may avoid the triggers. The study will be conducted on your smartphone through the doc.ai research app.

You must be honest with the study staff in order to participate in this research study. Please review this informed consent carefully.

SCOPE OF INVOLVEMENT

This research study is looking for approximately 200 participants diagnosed with MG living in the United States (US) who are willing to provide information (through the app) about their current symptoms if they have any, be willing to complete video and audio recordings to document their symptoms and keep a diary on their smartphone.

Enrollment will continue till we have analyzable data from at least 100 participants (participants complete their video and audio recordings, answer all the surveys, including the end of

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participation survey). 10-15 participants will be invited to do an interview after your participation ends to see what your experience was in using the app.

This smartphone-based self-enrolling study is expected to take up to nine months to enroll all participants. If you are enrolled in this study, for three months you will be asked to complete surveys and, video and audio recordings on your smartphone for 15-35 minutes each week.

VOLUNTARY PARTICIPATION

Your participation in this study is voluntary. There will not be any negative effect on you or your medical care if you do not participate. You do not lose any legal rights by signing this consent. This study does not provide treatment and your only other option is to not take part.

PROCEDURES

If you choose to participate, you must meet these inclusion criteria to be eligible.

- Must have a documented diagnosis of Myasthenia Gravis
- Must have ocular (eye drooping) and/or bulbar (speech) symptoms
- Must be over the age of 18
- Must reside in the US for the duration of the study
- Must be able to read, understand, and write in English
- Must have a smartphone to support the doc.ai research app (iOS or Android)

You were already asked on the pre-screening website some basic information to see if you qualified for this study. The recruitment tool for this study is developed for diversity, fairness, and inclusion. We aim to ensure diversity in the demographics of the study to better understand the health needs of different populations. Note that even if you qualify, you may not be invited into the study due to these diversity requirements.

After you sign this e-consent we will ask you more questions needed for this study.

You will be asked for information at the beginning to check your eligibility for the study.

- You will need to download the doc.ai research app on your smartphone, if you did not already do this.
- You will be asked to take a selfie on your phone. This feature is an Artificial Intelligence powered selfie that predicts physical characteristics data like age, gender, height, and weight. Your selfie image will only be used for this purpose.
- You will be asked if you met all the inclusion criteria listed above and to upload documentation of your MG diagnosis which clearly shows that the diagnosis is for you.
- If you wish, we will provide a phone resting stand to help you while completing the recordings at no additional cost to you. This will help you with completion of your video and audio check-ins easier (not having to hold the device steady for minutes at a time and to minimize shakiness), to increase video quality for analysis.

After you review this document and eSign it, the investigator will inform you if you are eligible to participate. The investigator may communicate with you via email.

Initial Check-in (approximately 5-20 minutes): This is to establish a baseline so we can understand how your symptoms present themselves and what medications you are taking. This will involve answering questions on your smartphone about your MG diagnosis and history.

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Daily Check-ins (approximately 1-2 minutes): This is keeping a symptom diary. You will have to answer questions about your general wellbeing and if you are experiencing any symptoms.

Twice a week Check-in (approximately 2-4 minutes): This will be to record your voice and face (on your smartphone) to see how your symptoms are. You will have to complete an approximately 1-minute video exercise and survey questions. These may include, but not be limited to these instructions to be completed within the session

- Vocal e.g.:
  - Say “papapapa” for 4 seconds
  - Say “tatatatata” for 4 seconds
  - Say “kakakaka” 4 seconds
  - Say “mamamama” 4 seconds
  - Say “papapapa” 4 seconds
  - Say “buttercup, buttercup, buttercup” 4 seconds
  - Say “aaaahhh” and hold it as long as you can
- Counting e.g.:
  - Look straight at the camera for 4 seconds
  - Count as precisely as possible from 1 to 25 while looking up
  - Look straight at the camera for 4 seconds
- Baseline sentences e.g.; say the following sentences:
  - Zoo passage: “Look at this book with us. It’s a story about a zoo.”
  - Rainbow passage: “The rainbow is a division of white light into many beautiful colors.”
  - Nasal sentences set: “Mama made some lemon jam.”

End of Week check-in (3-10 minutes): the same as the above (bi-weekly) audiovisual check-in, but also a questionnaire to see how your MG affects your quality of life and an interactive audiovisual diary check-in.

The more days you enter the information the better our chances of building an A.I model to predict MG symptom flares. We may reach out to you to remind you to complete your surveys if you delay the procedure by a few days.

After 3 months of doing this every week, your participation in this study will be complete and you will have to fill an end of study survey.

We may contact you for an interview after you finish the final survey to see what you thought about using the app, how easy or difficult you found the process to help us make improvements in our app. This interview will take about 45-60 minutes.

You will get a summary of your data at the end of the study to share with your personal doctor.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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WITHDRAWAL FROM STUDY

Taking part in this study is your choice. You have the right to leave this study at any time. If you do not want to be in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

If you wish to leave this study, please call the study investigator at the telephone number listed on the first page of this consent document to inform him.

Your part in this study may be stopped at any time without your permission. The following people can stop your participation and/or the study itself:

- Principal Investigator
- Sponsor Company
- Salus IRB
- The United States Food and Drug Administration (FDA)
- The United States Department of Health and Human Services (DHHS)

If you do not follow procedures, like completing the audio and video recordings and answering the surveys including the final survey, you may be taken out of the study by the PI. If you withdraw from the study, no new data about you will be collected for study purposes. The principal investigator will inform you whether he intends to either: (1) retain and analyze already collected data relating to you up to the time of your withdrawal; or (2) honor your request that your data be destroyed or excluded from any analysis.

RISKS

This is a data collection study, there are no physical risks to you. For this study the data will be stored on a HIPAA compliant cloud provider (Google Cloud Platform). The recorded videos and photos completed within the app will be stored within the doc.ai HIPAA compliant storage service.

BENEFITS

Based on this study additional studies may be designed in the future, which may help patients guess what affects their MG symptoms and so be able to control flare-ups better. You may not benefit directly by taking part in this study.

PAYMENT FOR BEING IN THE STUDY

The overall experience of the doc.ai app enables users to earn points through their actions in the app. Points will be collected on an ongoing basis by the participant within the app. Cumulative points for this study will be 25,000 points (collected after the participant completes all study required procedures, including the final survey). Participants in this study who complete all the actions can convert these total 25,000 points to a one-time only Amazon.com gift card of up to $250.00 in value through the link provided after the final survey.

You will be offered a phone stand approximately $10 in value, if you need it.

If you are invited to do the usability interview and complete the interview successfully, you will receive a one-time link for a total of $50, redeemable as a one-time Amazon.com gift card.

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The principal investigator is an employee of doc.ai on whose app this study is being conducted and is being paid by the sponsor to conduct this research study.

CONFIDENTIALITY

The results of this data study will be provided to the research sponsor, UCB Biopharma (SRL), all participants and may be presented at scientific or medical meetings or published in scientific journals. Your study records will be kept private. There may be times when the study investigator will not be able to guarantee privacy, such as when your study medical records are requested by a court of law or when shared with a firm in another country that does not have privacy regulations in place. Salus IRB, the FDA and accrediting agencies may inspect and copy your records, which may have your name on them. Therefore, your total privacy cannot be guaranteed. Your identity and/or your personal health information will not be disclosed. However, there is always some risk that even de-identified information might be re-identified.

Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to, medical history, other data provided.

All of the above information will be collected on personal phone via the doc.ai research app.

The study investigator may disclose your health information to the following persons and organizations for their use in connection with this research study:

- Sponsor Company
- Salus IRB
- The United States Food and Drug Administration (FDA)
- The United States Department of Health and Human Services (DHHS)

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

Access for study researchers to your health data must be explicitly granted by you and can include full access to the downloaded medical data in the app or medical or device data you've explicitly chosen to synchronize from 3rd-parties (e.g. Apple Health, your healthcare provider, Fitbit, etc.) . No other phone data, photos, contacts, emails or other information that has not been explicitly shared by you into the app will be available to the study or its researchers - in other words, the information on your phone and not in the study app will not be accessible even with granted permissions. Once data is entered or synchronized for the study, it will be accessible to the research team, but you will not be identified or linked to your data in any public presentation or publication, unless you have given specific written permission to do so. The study is designed to be HIPAA (Health Information Portability and Accountability Act) compliant. You can request this information from the principal investigator or study staff.

Salus IRB has approved this study and this informed consent document. Salus IRB is a committee of scientific and non-scientific individuals who review, require modifications to, and approve or disapprove research studies by following the federal laws. This group is also required by the federal regulations to provide periodic review of ongoing research studies.

You will be informed about any new findings which may affect your decision to participate.

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CONTACT INFORMATION

If you need medical attention, please go contact your own doctor or your nearest emergency room. This study does not provide any medical advice.

You may contact the principal investigator or study staff at the phone number listed on the first page of this consent document:

- for answers to questions, concerns, or complaints about this research study,
- to report a research related injury, or
- for information about study procedures.

You may contact Salus IRB if you:

- would like to speak with someone unrelated to the research,
- have questions, concerns, or complaints regarding the research study, or
- have questions about your rights as a research participant.

Salus IRB
2111 West Braker Lane, Suite 100, Austin, TX 78758
Phone: 855-300-0815 between 8:00 AM and 5:00 PM Central Time
Email: salus@salusirb.com

If you would like additional information about your rights, research in general, or IRBs, you may visit www.salusirb.com.

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AUTHORIZATION

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law.

By clicking the accept button here you are consenting to participate in this data trial, you are giving doc.ai access to your data and are confirming that you are the same person as the unique profile you have created in the doc.ai app.

_____
Date (auto-populated)

_____
Name Adult Participant (Auto-populated from account created on doc.ai research app)

_____
Email of Adult Participant (Auto-populated from account created on doc.ai research app)

_____
Name of Person explaining the consent (**if not self**)

A signed copy of this consent form will be emailed to you for you to keep.

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Initial Draft	dlh: 18Aug20	kw: 24Sep20	kw: 08Oct20