character

November 2024

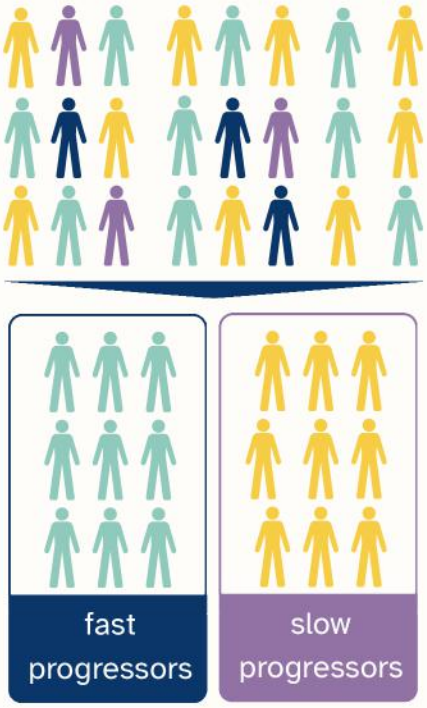
De-centralized Prospective Epidemiological Study of Progression of Age-Related Macular Degeneration (AMD):

Interim Results

www.characterbio.com

Table of Contents

Interim Results	01
Research Timeline	05
Frequently Asked Questions (FAQ)	07
Glossary of Terms	10
Character's Privacy Policy	12
Contact Information	14



Goals

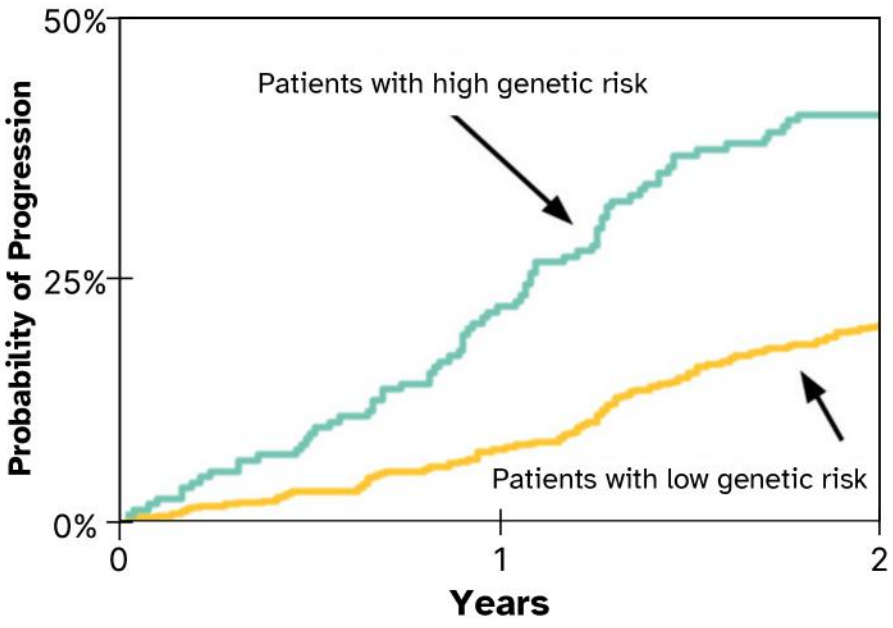
The main goal of our study is to better understand how genetics lead to differences in how fast or slow a person develops AMD. We also aim to understand how other factors, like a person's medical history (for example, taking certain medications) or behavior (for example, smoking) can make AMD progress faster or slower.

The ultimate goal of our AMD Research Program (which this study is a part of) is to create therapies that can treat AMD, and tests that can identify which patients might benefit the most from different therapies based on their genetic markers and medical history.

Key Findings

When we started the study in 2019, scientists had already identified 34 common genetic markers associated with AMD. Through the participation of the 5,000-plus patients in our study, we were able to identify new genetic markers that have never been associated with AMD before. These markers provide us with clues as to how and why AMD develops in certain patients. And in turn, we will use this knowledge to explore future therapies that target the biological pathways that these genes influence.

AMD Disease Progression by Genetic Risk



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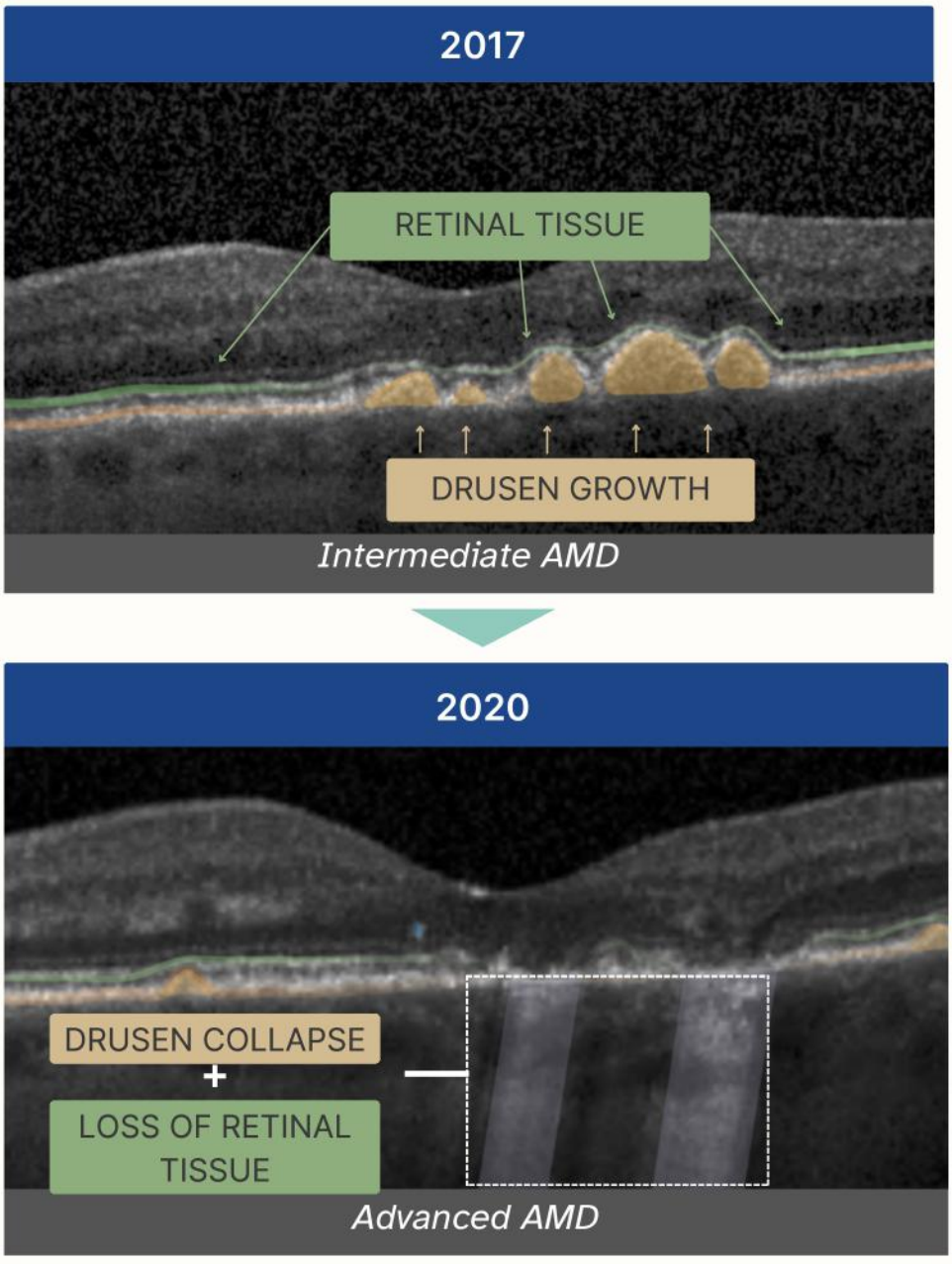
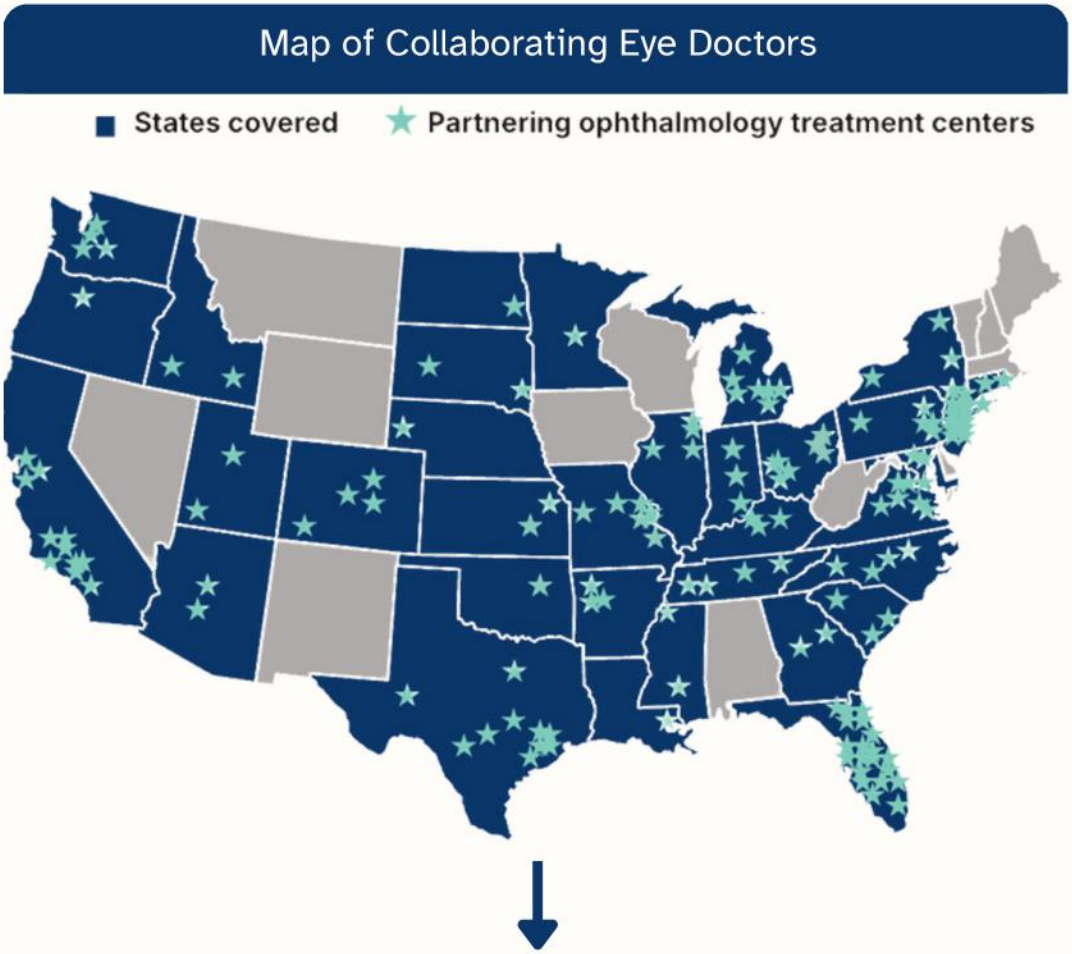
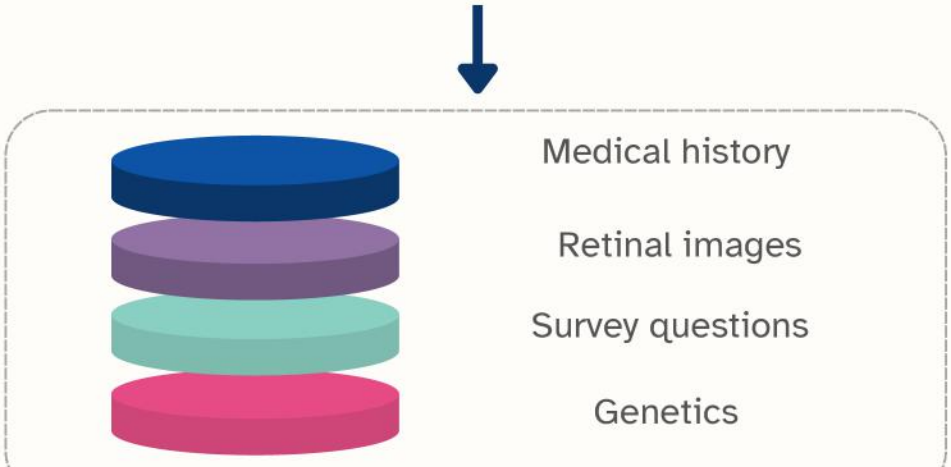
Beyond genetics, we learned a lot about AMD by analyzing the images of your retina taken at your doctor's office. We uncovered how different features on certain AMD patients' retinas might indicate a risk for losing their vision sooner than others. These findings are crucial to helping eye doctors identify patients who might be at risk; they can be identified quickly during a doctor's appointment and patients can be monitored or treated right away.



Above: images of an AMD patient's retina over time. Drusen, a buildup up of yellow deposits on the retina, can lead to the loss of retina tissue, and eventual vision loss.

As a result of what we learned, we developed two different therapies focused on slowing down the development of AMD. Starting this year, we will begin clinical trials to see how well our therapies work in patients.





Components of the Biorepository and Patient Registry

Methods and Approach

We were able to learn so much about AMD and develop therapies by creating the world's largest patient registry and biorepository of people with AMD. This has allowed us to study the eyes, genes, and medical histories of AMD patients to understand the disease better. Right now, you are part of the largest group of AMD patients to have ever been studied!

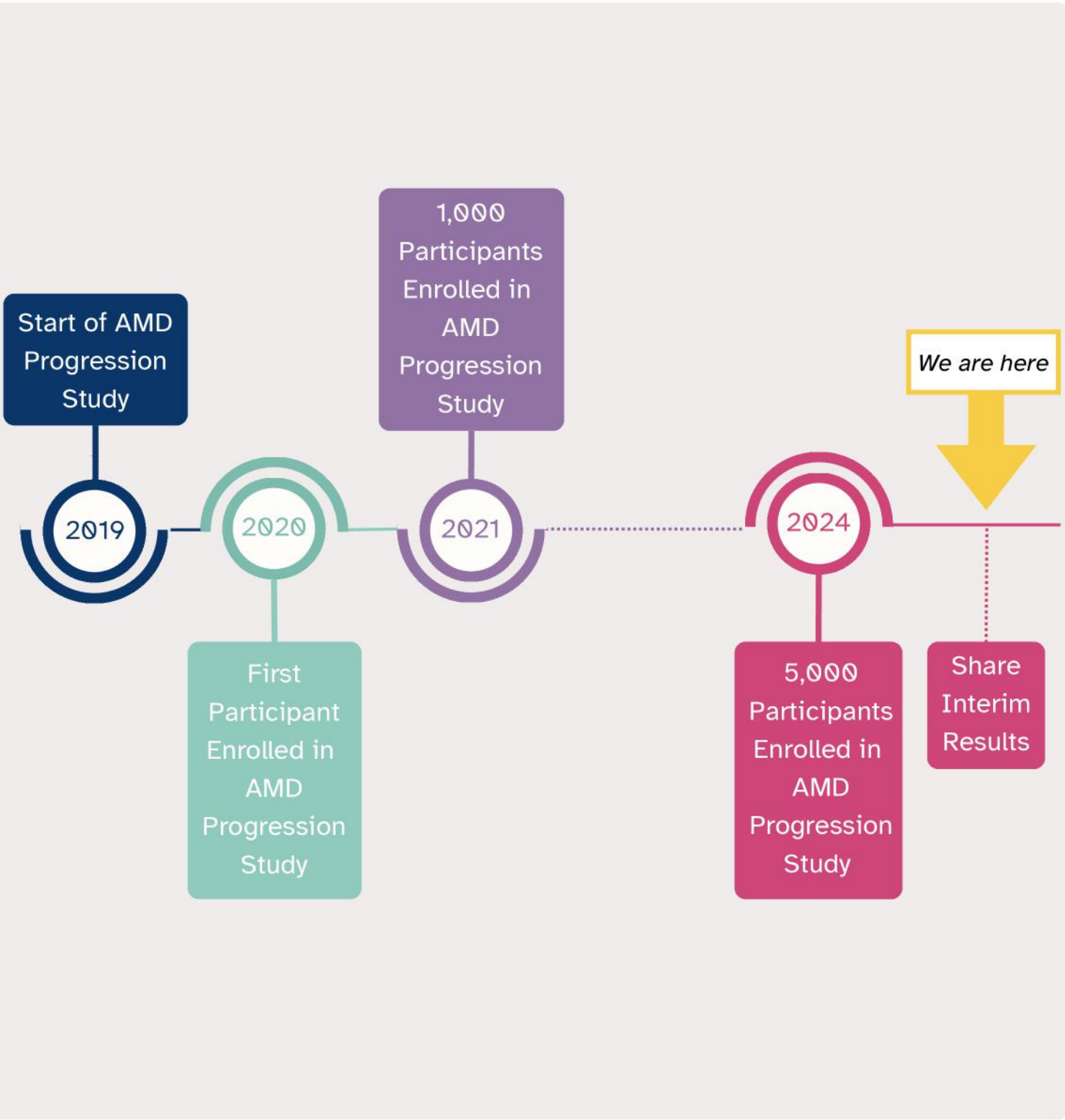
Next Steps

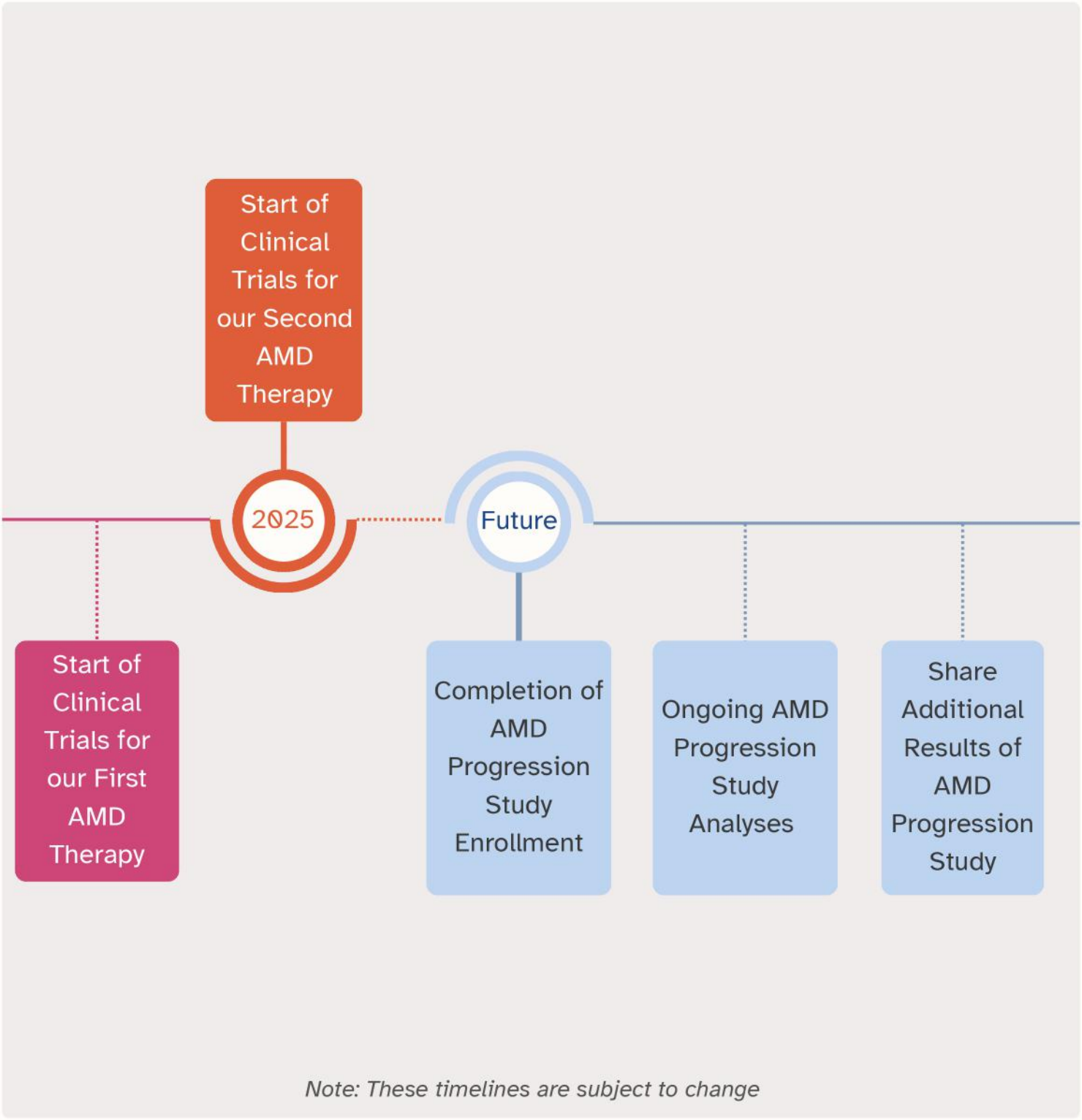
The next step is to continue to grow our study and patient registry. We plan to enroll up to 15,000 total participants in the study. By enrolling many different people with AMD, we hope to uncover additional genetic markers and other causes of the disease. This in turn will allow us to create even more therapies to treat the multiple types and stages of AMD. This approach is called “personalized medicine” and allows treatments to be tailored to patients. We believe we still have a lot more to discover about AMD, and hope we can treat as many people as possible!

As the results of the study come in, we will continue to share them directly with you, your doctor, as well as the larger scientific community. Please also check back on our website where we plan to post updates: **www.characterbio.com**

Scan the box above with your smartphone's camera to be taken directly to our website.

Research Timeline





Note: These timelines are subject to change

1. Will I receive my individual genetic test results?

The type of DNA testing we have performed on your saliva sample is called a "research use only" (RUO) test. These tests are important tools for a scientific investigation, but are not meant to diagnose a patient or to be used in a clinical setting, meaning your doctor's office. Because they are used for research only, your individual results cannot be returned to you.

Character Bio uses the RUO test results to discover important genetic markers that we think are associated with AMD. We plan to take the findings from our research, and develop a "diagnostic test." This test has to go through the same rigorous approval process with the Food and Drug Administration (FDA) as a new therapy. This process tests whether a) the test can accurately and precisely identify the genetic markers and b) the genetic markers are actually associated with disease in AMD patients.

Once approved, the diagnostic test results can be returned to patients and interpreted by doctors. Character Bio may use such a test to identify which patients should be prescribed which AMD therapy.

2. How can I receive the therapy that you are developing for AMD?

Before a therapy can be prescribed to patients, it first has to be tested for safety and efficacy in treating a disease through a series of clinical trials. The outcome of those trials is assessed by the FDA here in the U.S. This process can take a few years. Once a drug receives approval from the FDA, it can be made available to patients in the U.S. through a prescription from their doctor.

You can check back on our website for updates on this process at **www.characterbio.com**. We plan on keeping you up to date as soon as we have an approved therapy.

3. What is a “clinical trial”?

A clinical trial is a study where a new drug is tested to see if it’s safe and effective in treating a disease. Most therapies must go through a series of larger studies to support that the drug is safe and effective before they can be approved. Once the results of the clinical trial are in, scientists must submit them to a regulatory agency for review and approval. In the U.S., this is the FDA. Once approved, the therapy can be prescribed to patients by a doctor.

4. How will I know if I’m eligible for one of your clinical trials?

If you expressed interest in being contacted for future research opportunities during our initial call, you may hear from Character Bio or from your doctor in the coming months or years about an opportunity to participate in a clinical trial or other research opportunity.

Patient eligibility for our clinical trials may depend on multiple factors:

1. If your genetic background matches one of the therapies we’ve created;
2. If your stage of the disease and medical history matches our study requirements;
3. If your physician is set up to run a clinical trial and is interested in collaborating with us.

5. What other studies are you conducting?

We are also conducting a study to understand the differences in disease progression in people with glaucoma. This study is very similar to our AMD study in that we hope to learn about the genetics and medical history of these patients in order to create more effective therapies.

6. What other results should I expect?

As more discoveries are made from this study, we plan to keep you and your eye doctor informed. We will post updates on our website, which you can find here: https://www.characterbio.com/news. We will also send you information about the study once it is completed, which may be a few years from now.

Scan the box above with your smartphone's camera to be taken directly to our website where we post updates about this study and more.

Age-Related Macular Degeneration (AMD)	A problem with your retina. It happens when a part of the retina called the macula is damaged. With AMD you lose your central vision. It is a leading cause of vision loss in people 50 years or older.
Biorepository	A “library” of biological material and medical information scientists can use to learn more about the human body and develop new ways to improve health.
Drusen	Yellow deposits under the retina. Drusen are made up of lipids and proteins. Having these deposits is often a sign of AMD. Because drusen is visible on OCT images, it is one way an ophthalmologist can diagnose AMD.
Epidemiological	The study of how often diseases occur in different groups of people and why. Epidemiological research helps us to understand how many people have a disease or disorder, if those numbers are changing, and how the disorder affects our society.
U.S. Food and Drug Administration	A federal agency that protects public health by ensuring the safety of food, drugs, and medical devices.
Genetic marker	A DNA sequence with a known physical location on a chromosome. Genetic markers can help link an inherited disease with the responsible gene. The genetic marker itself may be a part of a gene or may have no known function.

Glossary of Terms

Macula	A small but important area in the center of the retina. You need the macula to clearly see details of objects in front of you, like faces and written text.
Optical coherence tomography (OCT)	A non-invasive imaging test. It uses light waves to take cross-section pictures of your retina. With OCT, your ophthalmologist can see each of the retina's distinctive layers. This allows them to map and measure layer thickness, and can help to diagnose and treat diseases like AMD.
Patient registry	A collection of data about patients who share a common disease, condition, or exposure. Patient registries use observational study methods to collect data over time.
Personalized medicine	An emerging practice of medicine that uses a person's genetic profile to guide decisions about prevention, diagnosis, and treatment of disease. Knowledge of a patient's genetic profile can help doctors select the proper therapy and administer it using the proper dose or regimen.
Retina	The layer of cells lining the back wall inside the eye. This layer senses light and sends signals to the brain so you can see.

We are accountable for protecting your privacy

This means that we ensure responsible data management and protection against any intentional or unintentional use, unauthorized access, disclosure, or re-identification of participants' data.

We are transparent about the use of your information

This means we ensure you remain adequately informed through all stages of participation in any Character research project.

We will communicate with you clearly and conspicuously concerning: how, when, and what information and specimens will be collected and stored; generally how your data will be used, accessed, and shared; types of studies for which your data may be used; the goals, potential benefits, and risks of participation, including risks of inappropriate use or compromise of your information; and your ability to withdraw from any research project at any time, with the understanding that consent for research use of data included in aggregate data sets or used in past studies and studies already begun cannot be withdrawn.

You always have the right to know what data is being collected and what it is being collected for.

We minimize the collection, use, processing, and storage of your information.

This means we only collect, use, process, and store your information that is directly relevant and necessary to accomplish a legitimate Character purpose, and only maintain your information for as long as is necessary to accomplish the purpose.

We respect your preferences

This means we promote your autonomy and trust through a dynamic and ongoing consent and information sharing process. This process enables you to engage actively in an informed and voluntary manner, and to re-evaluate your own preferences as data sharing, use requirements, and technology evolve.

You may withdraw your consent for future research use and data sharing at any time and for any reason, with the understanding that consent for research use of data included in aggregate data sets or used in past studies and studies already begun cannot be withdrawn.

We will never sell or use your data for targeted advertising

This means we will never sell, either directly or indirectly, your data for the purposes of advertisement or marketing. Additionally, we ensure partner organizations are contractually prohibited from utilizing any individualized data from our platform for the purposes of marketing.

We secure your data

This means we use known security best practices to ensure your data remains Confidential, Available, and Integral. Confidential means only authorized parties (based on need to conduct the research) are able to view the data. Available means the data is ready for access when necessary. Integral means no modifications are made to the data provided without your knowledge.

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