

# Reinventing Alzheimer's Disease Prescreening: The Global Alzheimer's Platform Foundation® (GAP) Remote Recruitment and Prescreening Program



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The Global Alzheimer's Platform Foundation® (GAP) is developing a program intended to make prescreening and recruitment events more accessible to potential Alzheimer's disease clinical trial participants.



Seniors are embracing telehealth technologies [1,2]



Remote recruitment and prescreening events address the transition to telehealth



Sites may have opportunities to be appropriately reimbursed for their prescreening activities

GAP's proposed multipronged strategy contains several elements designed to engage potential participants, enable prescreening, and maintain relationships with the community.

Programs	Tools
Remote recruitment toolkit	<ul style="list-style-type: none"> <li>• GAPTalks</li> <li>• eCommunication Platform reviews</li> <li>• Podcasts and support groups</li> <li>• Self-care resources for site staff</li> <li>• Connections with other GAP-Net sites</li> </ul>
Virtual prescreening toolkit	<ul style="list-style-type: none"> <li>• Technology setup and support</li> <li>• Virtual prescreening guidance and standards</li> <li>• Guidance documents and support</li> </ul>
Home visit "To Go" kit and phlebotomy certification	<ul style="list-style-type: none"> <li>• Basic materials necessary for site personnel to complete study procedures during an at-home study visit</li> <li>• Phlebotomy certification</li> </ul>
Education on billing opportunities for cognitive testing	<ul style="list-style-type: none"> <li>• White papers and reimbursement guides</li> <li>• Guidance on cognitive assessments</li> </ul>

Program implementation began late 2Q2020 in different venues.

## Initial Outcomes from First Quarter of Implementation



>800 attendees at 12 virtual talks



100 prescreens and 13 screens  
At a single site



Virtual and remote tools implemented in GAP-enabled clinical trial



CMS billing method implemented on small scale

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## Background

Many parts of clinical trials are moving toward a remote design to reduce COVID-19 exposure and transmission. Conventional recruitment and outreach events often involve direct contact with potential participants during memory clinics, brain health check-ins, or health fairs. Traditional prescreening processes often require a potential participant to travel to a research site for an initial appointment. For both prescreening and recruitment events, the usual challenges of getting the potential participant to the event or site due to distance, time constraints, and access to transportation have now been further compounded by increased potential for exposure to COVID-19. Potential participants in Alzheimer's disease (AD) clinical trials are especially vulnerable due to their age. Furthermore, AD trials typically require a study partner, so the potential for exposure has now been doubled.

The Global Alzheimer's Platform Foundation® (GAP) is developing a comprehensive remote recruitment and prescreening program for sites in its network (GAP-Net) that protects the safety of the clinical trial community while generating interest in clinical research and enabling collection of robust prescreening data. This program is designed not solely as a contingency during the COVID-19 pandemic but as a long-term strategy to make recruitment and prescreening events more accessible to potential AD participants.

## Objectives

The objectives of the GAP Remote Recruitment and Prescreening Program are as follows:

- Protect the health and safety of potential participants and clinical research personnel.
- Comply with the Health Insurance Portability and Accountability Act (HIPAA) and protect sensitive health information.
- Deliver remote recruitment and outreach processes / materials that enable sites to generate potential candidates for AD clinical research.
- Identify participants that are well-characterized for AD clinical trials and retain the interest of those participants.
- Ensure essential, user-friendly prescreening technology is available to sites and participants.
- Recommend a pathway for potential reimbursement of prescreening efforts under appropriate federal regulations.

## Methods

GAP's proposed multipronged strategy contains several customizable elements designed to engage potential participants, enable prescreening, and maintain relationships with the community.

**Remote recruitment toolkits** facilitate community engagement and stimulate interest in AD clinical research and brain health. Toolkits focus on telehealth options, e-communication platforms, and virtual strategies for staying connected to participants and the community. Among these are **GAP-facilitated events** such as GAP-Talks, which connect with potential participants on behalf of GAP-Net sites to provide education and awareness about Alzheimer's and Brain Health. GAP also focuses on **information sharing across sites** regarding what is working effectively by hosting regular webinars for GAP-Net sites to connect with one another and share ideas. GAP works with sites to develop remote workshops, educational lectures, Town Halls, brain health activities, and other virtual options to maintain a steady recruitment cadence. GAP-Net sites are also focusing **on social and digital media campaigns** to direct individuals to site websites, trial landing pages, and online intake forms.

The **prescreening toolkit** includes a detailed implementation roadmap for sites and participant-facing materials explaining the prescreening journey.

**Technology guidance** regarding HIPAA-compliant telehealth video applications is provided, as is technology (laptops, iPads) when possible, to ensure sites have the necessary telehealth equipment.

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## Methods (continued)

The **home health visit kit** that contains basic materials necessary for site personnel to complete trial procedures during an at-home study visit.

GAP also facilitates **phlebotomy certification** to expand capabilities of sites to complete home visits.

**Education on billing opportunities for cognitive testing** based on Centers for Medicare and Medicaid Services (CMS) regulations is also available so sites can learn about opportunities to be appropriately reimbursed for their prescreening activities.

## Results

Program implementation began late 2Q2020 in different venues. Results from the first quarter of implementation include the following:

- Over 800 people have participated in 10 virtual talks (hosted by GAP and GAP-Net sites) and even have received materials from the events. Prescreening has been offered at some events. Attendees are also registering for future events.
- 92% of GAP-Net sites in 1 GAP-enabled trial have successfully converted some or most of their processes to be virtual. GAP-Net sites recently implementing virtual prescreening programs have already seen a return to pre-pandemic prescreening rates. One GAP-Net site had 100 prescreens in July and August 2020 that resulted in 13 screens. These outcomes were comparable to those observed prepandemic.

## Results (continued)

- Pharmaceutical company sponsors are becoming increasingly receptive to virtual and remote recruitment, outreach, and trial execution. In 1 GAP-enabled trial, sites are being provided the virtual recruitment and prescreening toolkit and participating GAP-Net sites are being provided with a home health visit kit and phlebotomy certification.
- A CMS billing method (including process and coding education) is being performed on a small scale at 1 GAP-Net site in CA. GAP is collaborating with the site to collect data on implementation and outcomes. GAP will use the information to improve the effectiveness of a potential larger-scale implementation.

The Program will continue to be refined as additional elements are implemented.

## Conclusions

GAP-Net sites can effectively recruit and prescreen in a remote and virtual environment when provided information, support, and resources. Additional opportunities for more advanced programming may be included for support on specific trials, including kits to facilitate home health visits, where appropriate and approved.

## Conclusions (continued)

GAP's Remote Recruitment and Prescreening Program will provide the field with several benefits.

- A mechanism for remote prescreening will allow sites to continue to prescreen while protecting the health and safety of the clinical trial community.
- A cohort of potential participants that are well-characterized and willing to participate in AD clinical research, which can lower screen fail rates and accelerate enrollment.
- The remote prescreening process will help offset delays experienced because of the COVID-19 pandemic.
- Virtual or remote prescreening has allowed sites to continue to prescreen during COVID-19. Noteworthy is a single case study has shown an increase in the efficiency, the number of prescreens being completed and identification of qualified AD participants being screened.
- Finally, the program will provide much needed liquidity to AD clinical trial sites.

## References

1. Hackett M. Survey shows seniors are embracing technology and telehealth during pandemic. MobiHealthNews. 10 August 2020. <https://www.mobihealthnews.com/news/survey-shows-seniors-are-embracing-technology-and-telehealth-during-pandemic>. Accessed 22 September 2020.
2. Landi H. From telehealth visits to digital pharmacies, seniors have ramped up technology use during COVID-19: survey. Fierce Healthcare. 05 August 2020. <https://www.fiercehealthcare.com/tech/from-telehealth-visits-to-digital-pharmacies-seniors-have-ramped-up-technology-use-during>. Accessed 22 September 2020.