

# Removing Barriers to Alzheimer's Disease Clinical Trial Execution: GAP Rater Certification Program

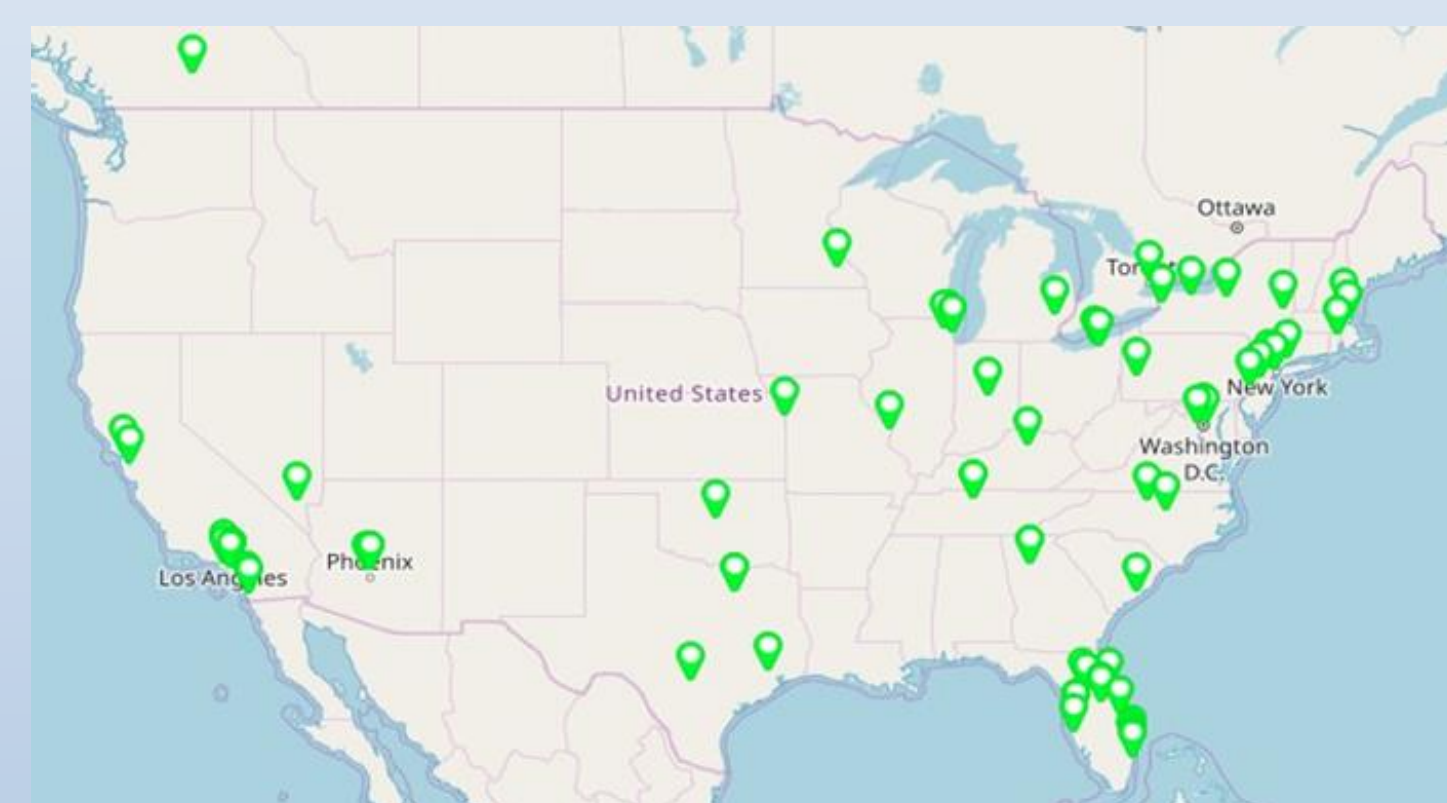
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## Introduction

The current rater qualification process usually requires raters to be re-trained for every new trial and limits the ability for new raters to become qualified.

- Rater training is time consuming and often repetitive / redundant from one trial to another. Redundant training consumes time of previously qualified raters, unnecessarily delays the collection of data, and adds no discernible value to the quality of rating data.
- Raters are required to complete rater evaluation surveys (RES) for each trial. RES limit the additional / explanatory information that can be included.
- Rater training / certification programs are often too restrictive in allowing new raters to get certified, severely hampering the rater pool at sites.
- Rater turnover can significantly impact ongoing trials and a site's decision to accept a new trial.
- 35% of the GAP-Net sites have turned down a trial due to lack of qualified raters!**

## GAP Site Network



## Methods

In collaboration with sponsors, sites, academic site networks, and scale developers, the Global Alzheimer's Platform (GAP) Foundation is investigating ways to accelerate rater training, minimize re-training for experienced raters, and increase the pool of qualified raters in its network of high-performing sites (GAP-Net). Universal qualification standards are being developed for rater certification across multiple scales. Raters will be certified through an exemption exercise for proven raters, targeted scale training for experienced raters, and full scale training for less-experienced / developing raters (Figure 1).

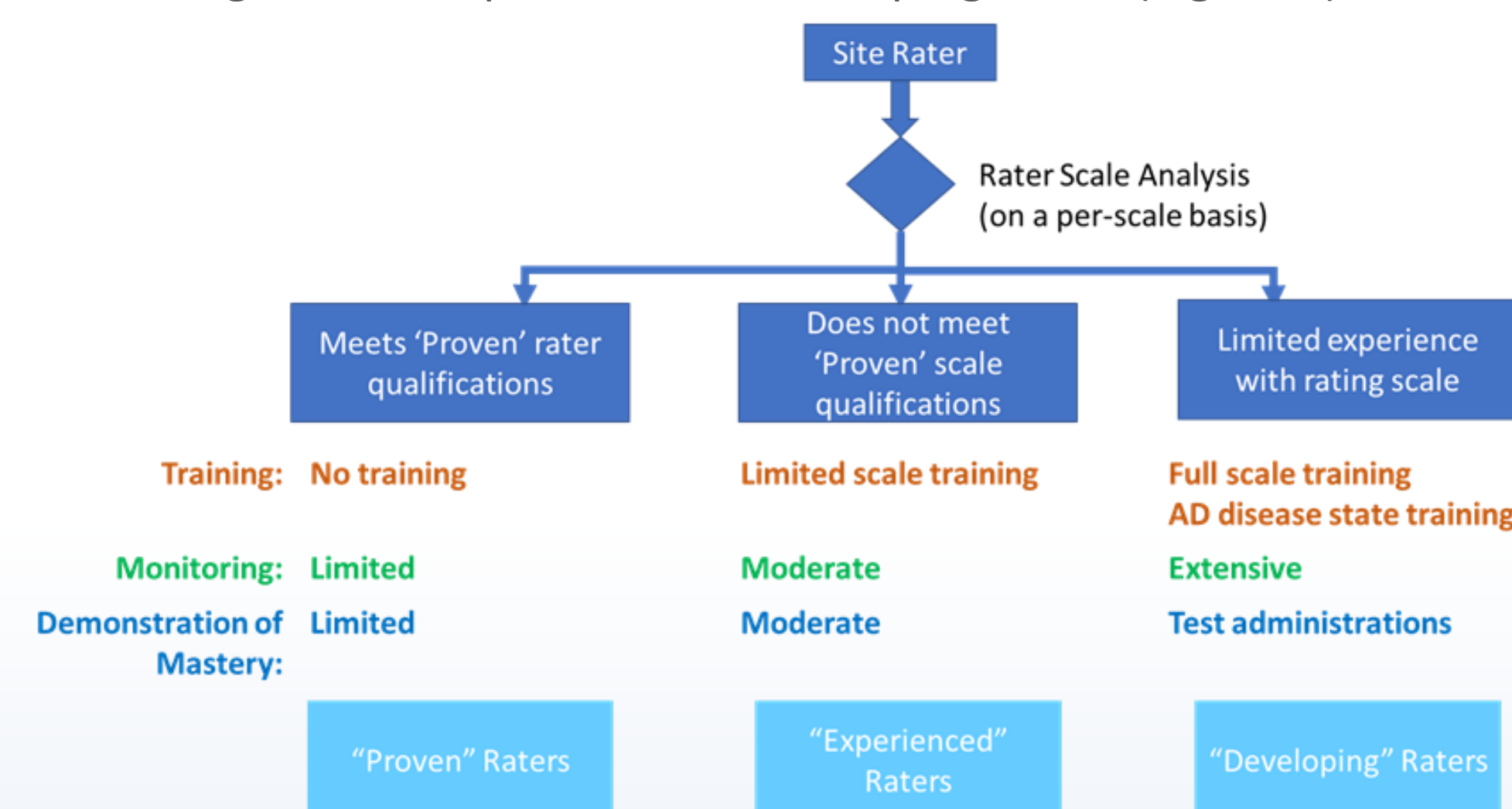


Figure 1: Targeted Rater Scale Qualification and Training Determination

Technology solutions are also being explored to enable centralized maintenance of rater qualifications and eliminate the need to complete a RES for every trial. Sponsors, CROs, and vendors will have access to the centralized database to review the most recent rater profiles (Figure 2).

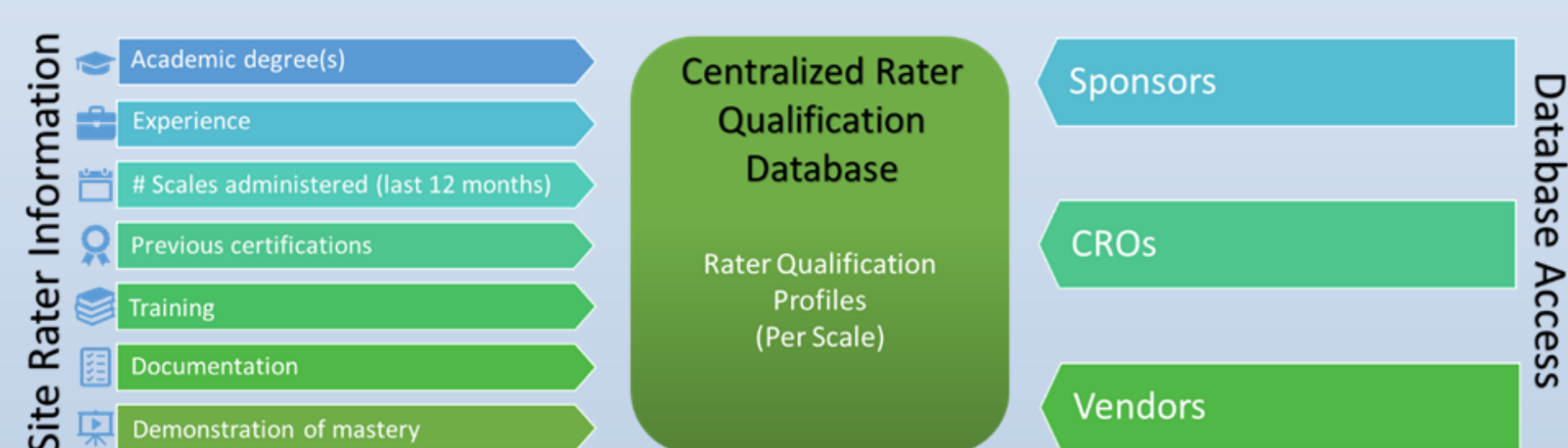


Figure 2: Centralized Rater Qualification Database

## GAP Rater Certification Program

**Universal qualification standards are being developed for the following 10 commonly used Alzheimer's disease clinical trial scales to streamline the rater qualification process:**

### Neuropsychological

- ADAS-COG
- MMSE
- RBANS
- FCSRT
- WMS-IV-LM
- WAIS-IV-DSC

### Functional

- ADCS-ADL
- FAQ

### Clinical Comprehensive

- CDR-SB
- Psychiatric Symptom
- NPI

The GAP-Net Rater Certification Matrix (Figure 3) defines scale-specific standards for proven raters and experienced raters as well as developing raters. Standards are based on education, experience, previous certification, and demonstration of mastery. Qualification will occur on a scale-by-scale basis. Raters may be 'proven' on one scale but 'developing' on another. Initial certification will be effective for one year; re-certification will be effective for two years. New raters may transition to experienced or proven category if all requirements are met. Raters may be automatically re-certified if rater proves excellence through video / audio monitoring near the end of their certification period. GAP will collect data on the quality of ratings obtained from raters certified through this process.

GAP-Net Rater Certification Matrix		CDR-SB*	ADAS-Cog	FCSRT	NPI	RBANS	ADCS-ADL	MMSE	FAQ	WMS-IV-LM	WAIS-IV-DSC	
<b>Proven Rater</b>		CDR-SB*	ADAS-Cog	FCSRT	NPI	RBANS	ADCS-ADL	MMSE	FAQ	WMS-IV-LM	WAIS-IV-DSC	
Degree		MD, PhD in any field, PsyD, MA or MS in a scientific or health related field, BA/BS in psychology or social work, BSN or RN										
Patient experience with dementia in a clinical or research setting, psychometric experience, or evidence of disease state knowledge		≥ 1 years, or evidence from site training of disease state knowledge and patient experience										
# of scale administrations (in past 12 months)		15	15	15	10	15	10	10	10	10	10	
Previous certification		Certification completed within past 12 months										
Training on scoring and administration		No	No	No	No	No	No	No	No	No	No	
Documented practice administrations		No	No	No	No	No	No	No	No	No	No	
Demonstration of mastery		V/A	V/A	V/A	N/A	V/A	N/A	V/A	N/A	V/A	V/A	
<b>Experienced Rater</b>		CDR-SB*	ADAS-Cog	FCSRT	NPI	RBANS	ADCS-ADL	MMSE	FAQ	WMS-IV-LM	WAIS-IV-DSC	
Degree		MD, PhD in any field, PsyD, MA or MS in a scientific or health related field, BA/BS in psychology or social work, BSN or RN										
Patient experience with dementia in a clinical or research setting, psychometric experience, or evidence of disease state knowledge		≥ 1 years, or evidence from site training of disease state knowledge and patient experience										
# of scale administrations (in past 12 months)		10	10	10	10	10	10	10	10	10	10	
Previous certification		Certification not completed within past 12 months										
Training on scoring and administration		Abbreviated didactic training, target training as needed										
Documented practice administrations		No	No	No	No	No	No	No	No	No	No	
Demonstration of mastery		V/A	V/A	V/A	Q	V/A	Q	V/A	Q	V/A	V/A	
<b>Developing Rater</b>		CDR-SB*	ADAS-Cog	FCSRT	NPI	RBANS	ADCS-ADL	MMSE	FAQ	WMS-IV-LM	WAIS-IV-DSC	
Degree		MD, PhD in any field, PsyD, MA or MS in a scientific or health related field, BA/BS in psychology or social work, BSN or RN										
Patient experience with dementia in a clinical or research setting, psychometric experience, or evidence of disease state knowledge		< 1 year experience working with any cognitively impaired population										
# of scale administrations (in past 12 months)		< 10	< 10	< 10	< 10	< 10	< 10	< 10	< 10	< 10	< 10	
Previous certification		Certification not completed within past 12 mos										
Training on scoring and administration		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
Documented practice administrations		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
Demonstration of mastery		Wash U/V	V/A	V/A	V/A	V/A	V/A	V/A	Q	V/A	V/A	
<b>Demonstration of Mastery</b>		Shorthand		Description								
Video/Audio		V/A		Rater to administer scale to mock subject while being observed by an expert								
Scoring Exercise		SE		Rater provided completed assessment to score and submit								
Administration and Scoring		A&S		Rater to watch administration video and score								
Quiz		Q		Rater to answer questions on general scoring and administration guidelines								
Not Applicable		N/A		No demonstration of mastery required								

Figure 3: GAP-Net Rater Certification Matrix

## Conclusion

Rater certification is a key component in successful study start up and trial execution, but the current rater certification process is time consuming and redundant between trials. GAP proposes universal qualification standards across multiple scales to realize the following benefits:

- Improved site acceptance of a trial
- Accelerated rater training
- Increase in the pool of qualified raters
- Streamlined process for qualifying raters before and during a trial
- **Ultimately speed study start up**

GAP expects to initiate an early version of the program in one of the next GAP-enabled trials in a subset of sites in 4Q2019.

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