

Beyond Patient Journals - Using GAS to Capture the Patient Voice

Individualized Outcomes in the DEE Population
November 4th, 2021



ARDEA

OUTCOMES

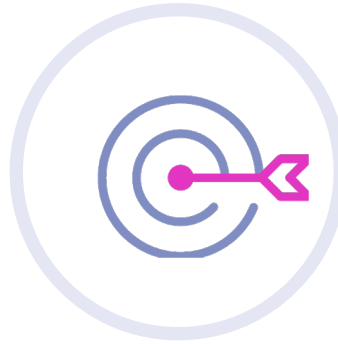
GOAL ATTAINMENT SCALING
MEASURES THE EXTENT TO
WHICH A PATIENT'S
INDIVIDUAL GOALS ARE
ACHIEVED WITH
INTERVENTION.

Goal Attainment Scaling is a three step process.



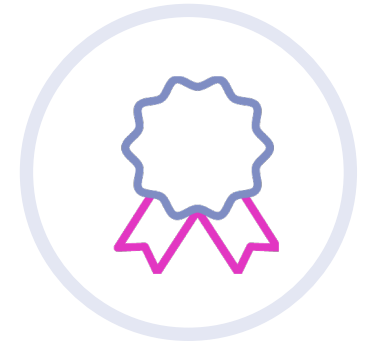
IDENTIFY GOALS

Clinician to facilitate interview for subject or caregiver to identify goals



BUILD GAS SCALES

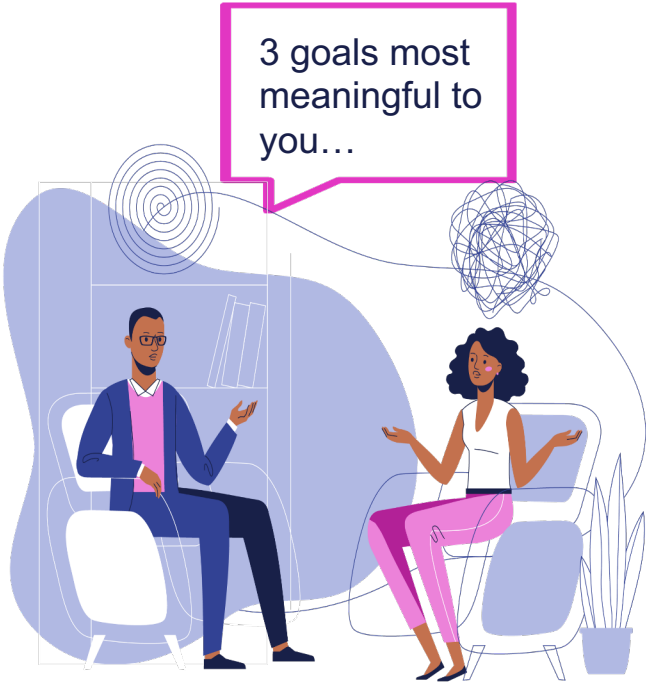
Set the 5-point goal attainment scale for each identified goal



MEASURE ATTAINMENT

Rate during follow-up whether the goals have been attained

The Goal-Setting Visit focuses on what is important to the participant.



Goal Title



Much Better than the Goal



+2

Somewhat Better than the Goal

+1

The Goal

0

Baseline Status

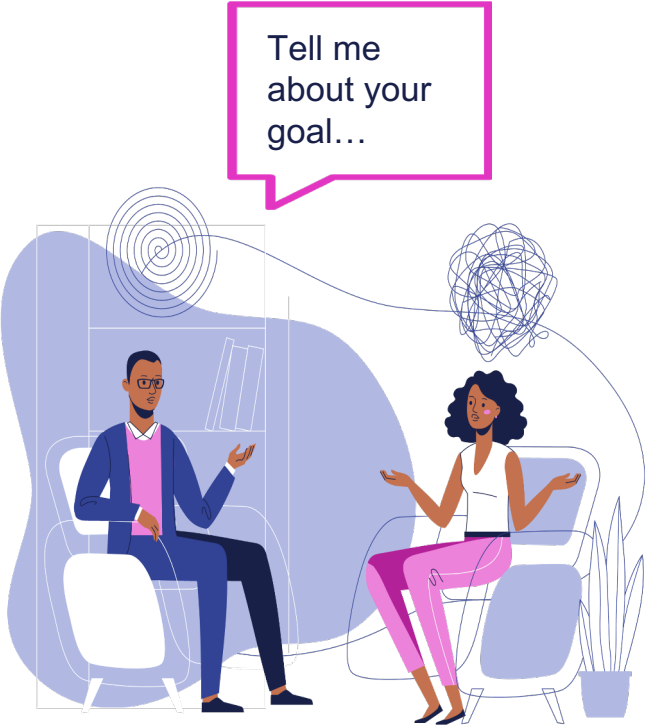
-1

Much Worse than the Goal

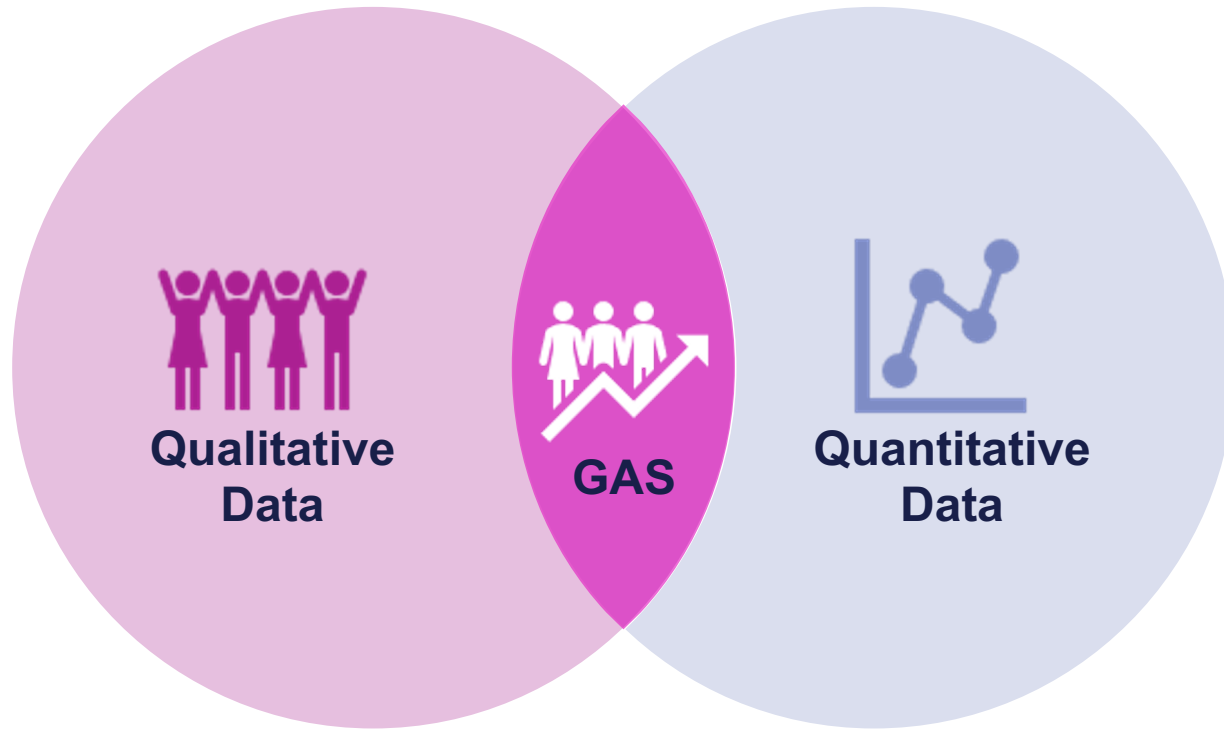
-2

During Follow-Up Visits clinicians and participants rate goal attainment.

	Subject Rating	GAS Interviewer Rating
Much Better than the Goal Ut enim ad minim veniam, quis nostrud exercitation ullamco laboris nisi ut aliqui.	<input type="radio"/> +2	<input type="radio"/> +2
Somewhat Better than the Goal Ut enim ad minim veniam, quis nostrud exercitation ullamco laboris nisi ut aliquip ex ea commodo consequat.	<input type="radio"/> +1	<input type="radio"/> +1
The Goal Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Ut enim ad minim veniam, quis.	<input type="radio"/> 0	<input type="radio"/> 0
Baseline Status Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor.	<input type="radio"/> -1	<input type="radio"/> -1
Much Worse than the Goal Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor.	<input type="radio"/> -2	<input type="radio"/> -2

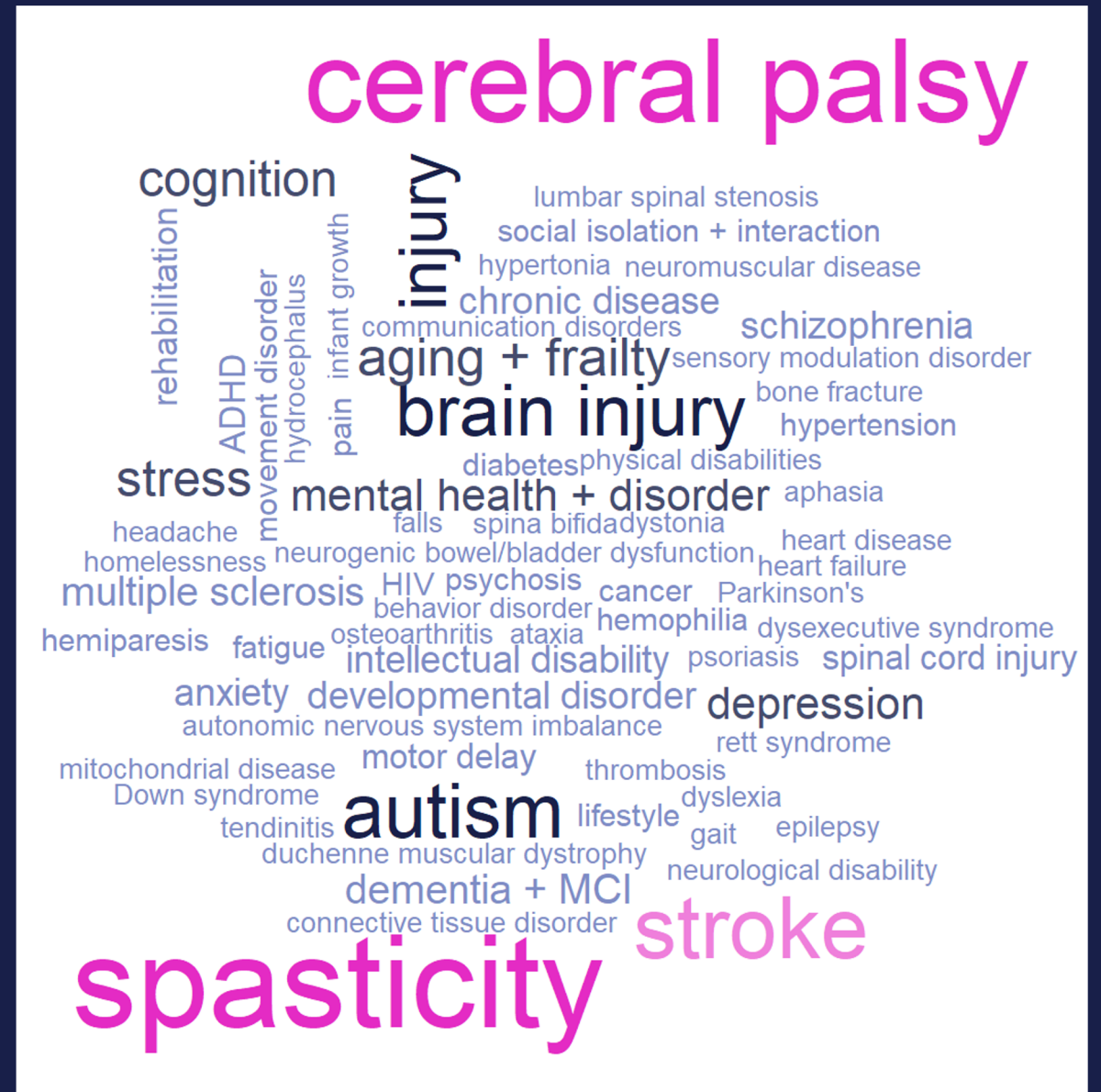


GAS data has multiple layers of interpretation



Where quantitative and qualitative meet to measure efficacy and effectiveness

GOAL
ATTAINMENT
SCALING IS
GAINING
PROMINENCE IN
RESEARCH.



GAS provides value throughout the clinical development lifecycle.

PHASE 01

PHASE 02

PHASE 03

PHASE 04

➤ GAS is a **Patient-Centric Outcome Measure**

➤ GAS may be used Phase 1B onward

Phase 4 → Reported by patients as a PRO/RWE

Phase 1→4: GAS is facilitated by a Clinician: some similarities to a Clin-RO but coming from the patient

Best **introduced early**
in clinical development

Data shows **efficacy**
and **effectiveness**

Data is **inherently**
clinically meaningful
and relevant

Modified GAS data
captured direct from
patients or caregivers

✓ Changes the nature of the dialogue
between patient and clinician

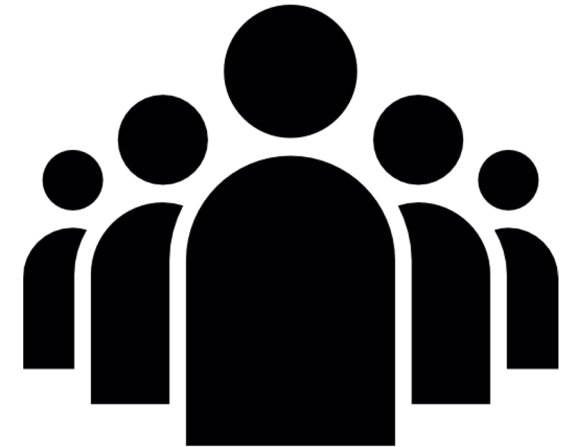
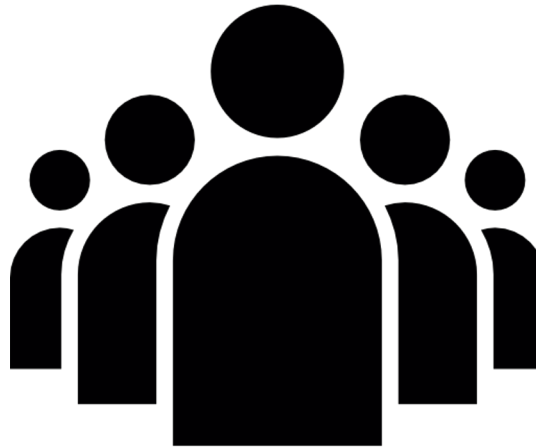
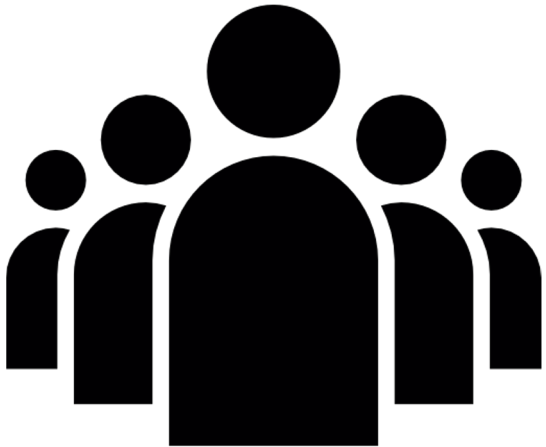
✓ GAS data is meaningful to patients,
caregivers, sponsors and regulators

✓ Promotes shared decision-making
✓ Incorporates wishes and concerns of
patients or caregivers

✓ GAS is motivating
✓ GAS can promote adherence

Ardea Outcomes PCOR Experience

- Hip fracture
- Rehabilitation
- Dementia (MCI, mild, moderate and severe AD)
- Dementia with Lewy Bodies
- Down Syndrome – Associated AD
- Parkinson disease
- Schizophrenia
- Hemophilia
- Neurogenic Bladder and Bowel Disorders
- Rare Oncology
- Prader Willi Syndrome
- Autism



Ardea Products and Services

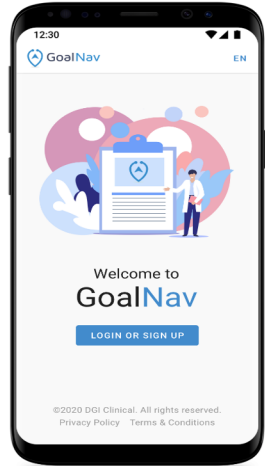
RESEARCH SERVICES

- Study design
- Protocol development
- Instrument development
- Data analytics
- Medical writing



TECHNOLOGY

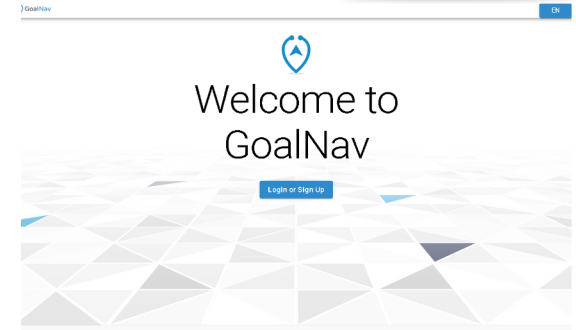
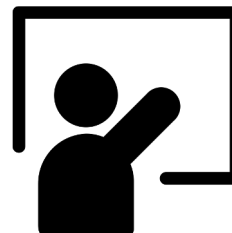
- FDA 21 CFR Part 11 Compliant EDC
- GDPR standard data privacy and security
- Built for clinical trials, patient registries, and patient support programs
- User Support



**POWERED BY
Goal Attainment
Scaling**

TRAINING

E-learning system, webinars, and F2F training for sponsors, investigators, study team, monitors



Caregivers' Perspective: Down syndrome- associated Alzheimer disease

1

Literature Review:

Identification of the most common dementia symptoms and challenges within the Down syndrome population

2

Expert Clinician Input:

Review of draft menu was completed during two meetings with a total of four expert clinicians in Down syndrome

3

Caregiver Interviews:

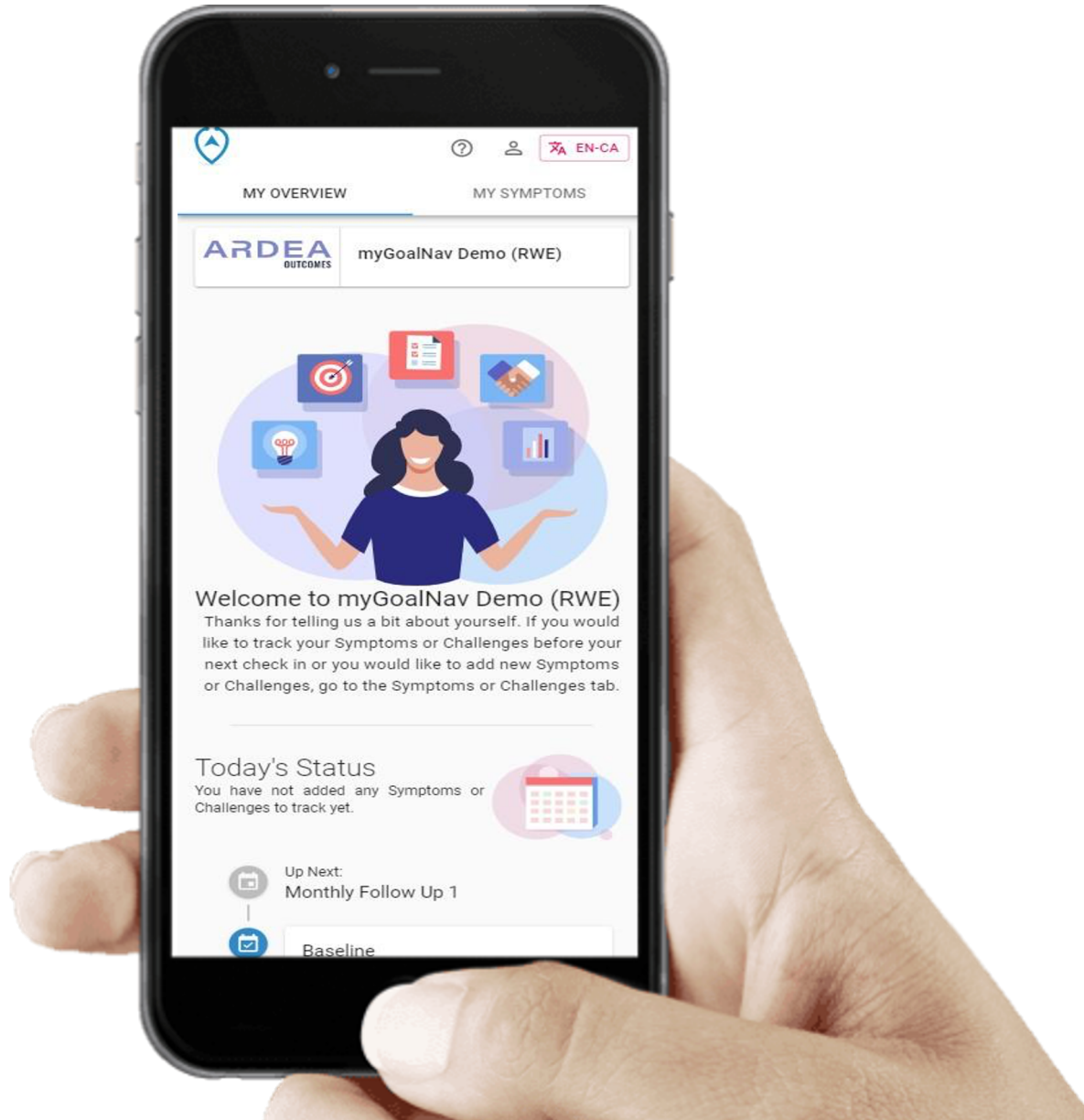
Ten caregivers of people with Down syndrome participated in online semi-structured interviews; open-concept elicitation of symptoms related to dementia in Down syndrome and review of the menu for clarity and comprehensiveness

4

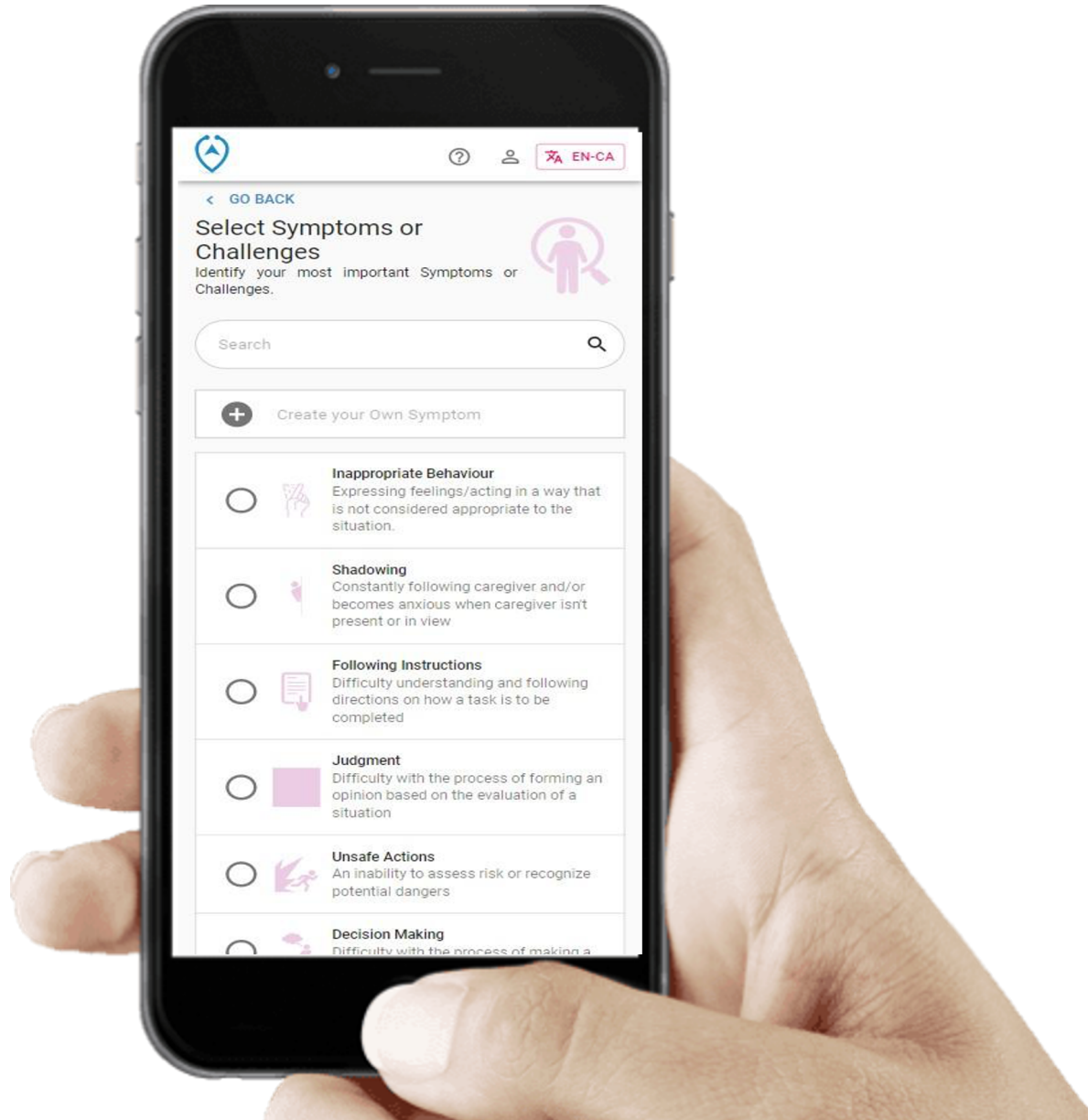
myGoalNav configuration:

Configure EDC system for GAS and other endpoint data capture.

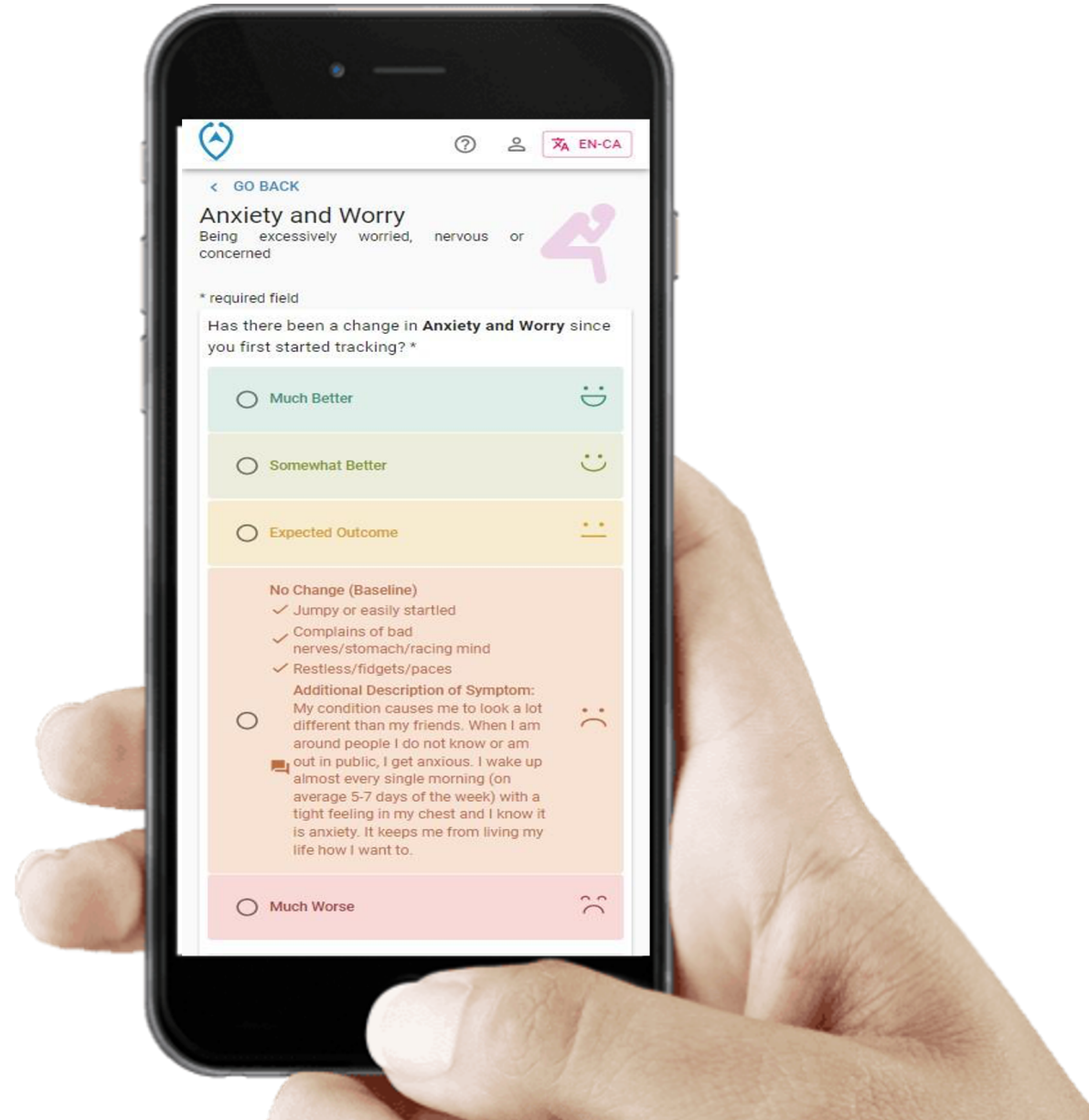
GAS in Action - Shared Decision-Making



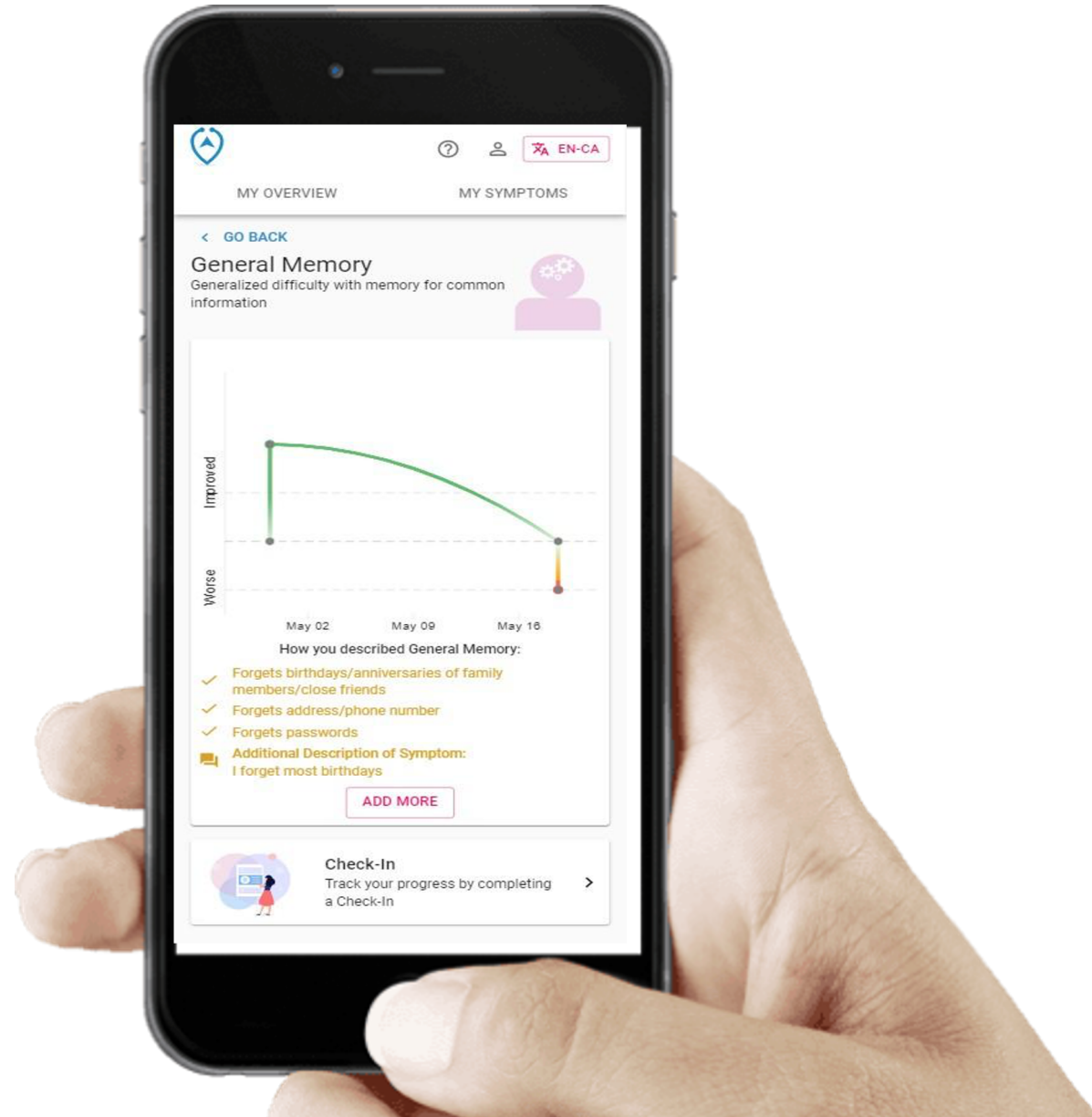
GAS in Action - Shared Decision-Making



GAS in Action - Shared Decision-Making



GAS in Action - Shared Decision-Making



Proposed Next Steps

Developing and Piloting a GAS Outcome in the DEE Population

1. Develop early GAS menu from literature

1. Elicit input from experienced clinicians

1. Perform patient voice study with proxy informants - interviews, focus groups

1. Finalize semi-standardized goal menu

1. Develop key study documents
 - Protocol
 - GAS statistical analysis and data management plans
 - Goal quality assurance plan

1. Adapt GAS training materials

1. Configure and test the GoalNav EDC

1. Train all clinic and study staff on Goal Attainment Scaling method and use of GoalNav® EC

1. Perform goal quality assurance during screening and baseline

2. Provide ongoing support for GAS and use of GoalNav® EDC

3. Perform data analysis and data interpretation

1. Disseminate results

Development of the GAS Endpoint

GAS Pre-Study Preparation

GAS Study Initiation and Execution

Thank you.
Ardea Outcomes.

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