

A Review of Goal Attainment Scaling Implementation as a Personalized Clinical Outcome Assessment over the Last Decade

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Background

GAS is a personalized endpoint that quantifies the effects of an intervention on individualized goals.¹

Clinicians or disease experts work with patients or caregivers to identify personal goals (symptoms and challenges) that are meaningful to the patient.

After goals are selected, a 5-point scale is developed for each goal. The scales are personalized and have granularity to assess incremental changes. As such, GAS avoids floor and ceiling effects and adequately discerns treatment benefits.

It is particularly valuable for conditions with heterogeneous symptoms and impacts where standardized measures may lack the sensitivity to capture meaningful change.

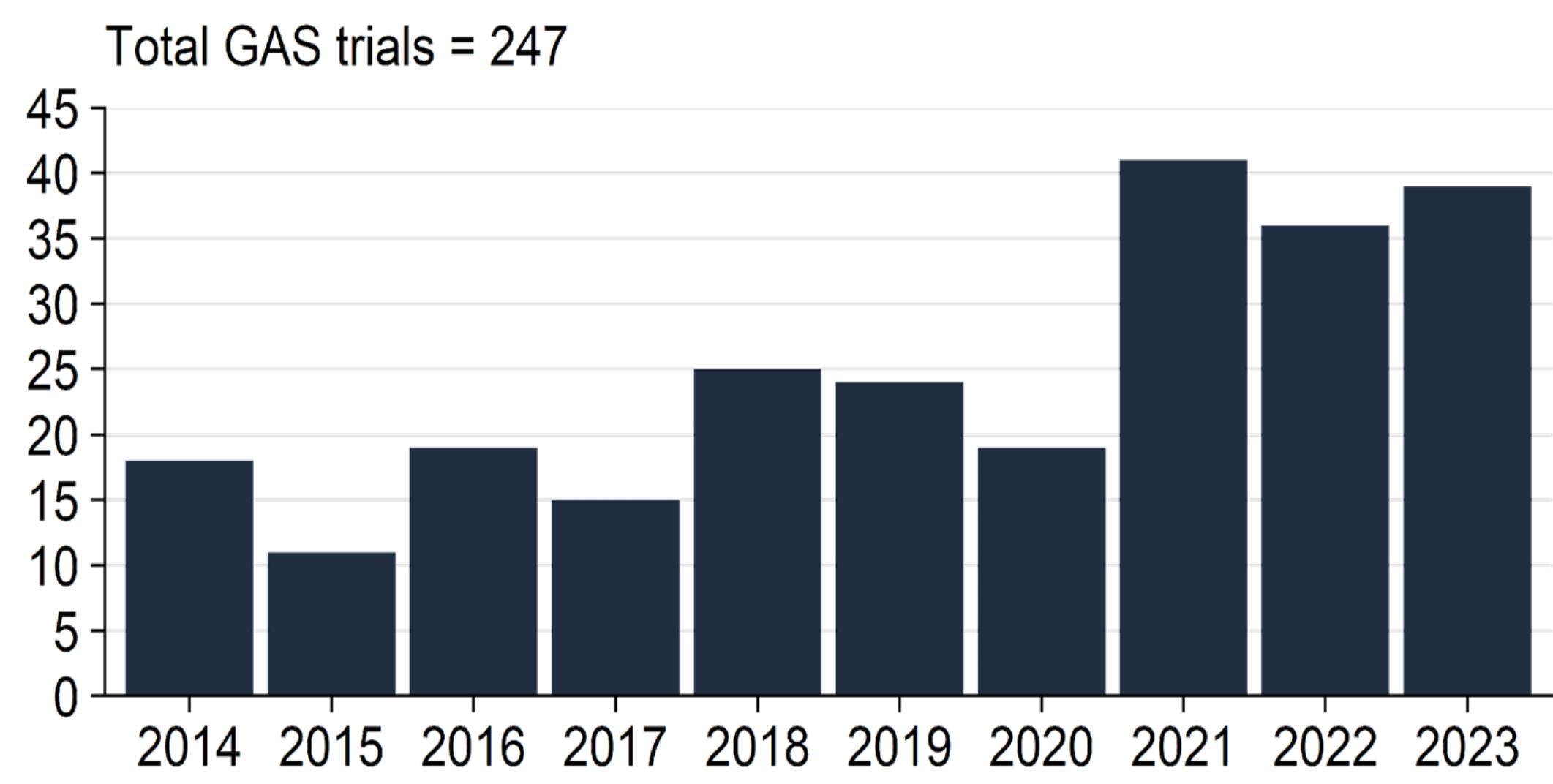
We reviewed a decade's use of this personalized endpoint in clinical trials.

Results

263 trials were initially identified, and 16 were excluded since GAS was not used as an outcome.

Nearly half (112, 45%) of the trials were completed; 35% were ongoing (pre-recruitment, recruiting, enrolling, or active).

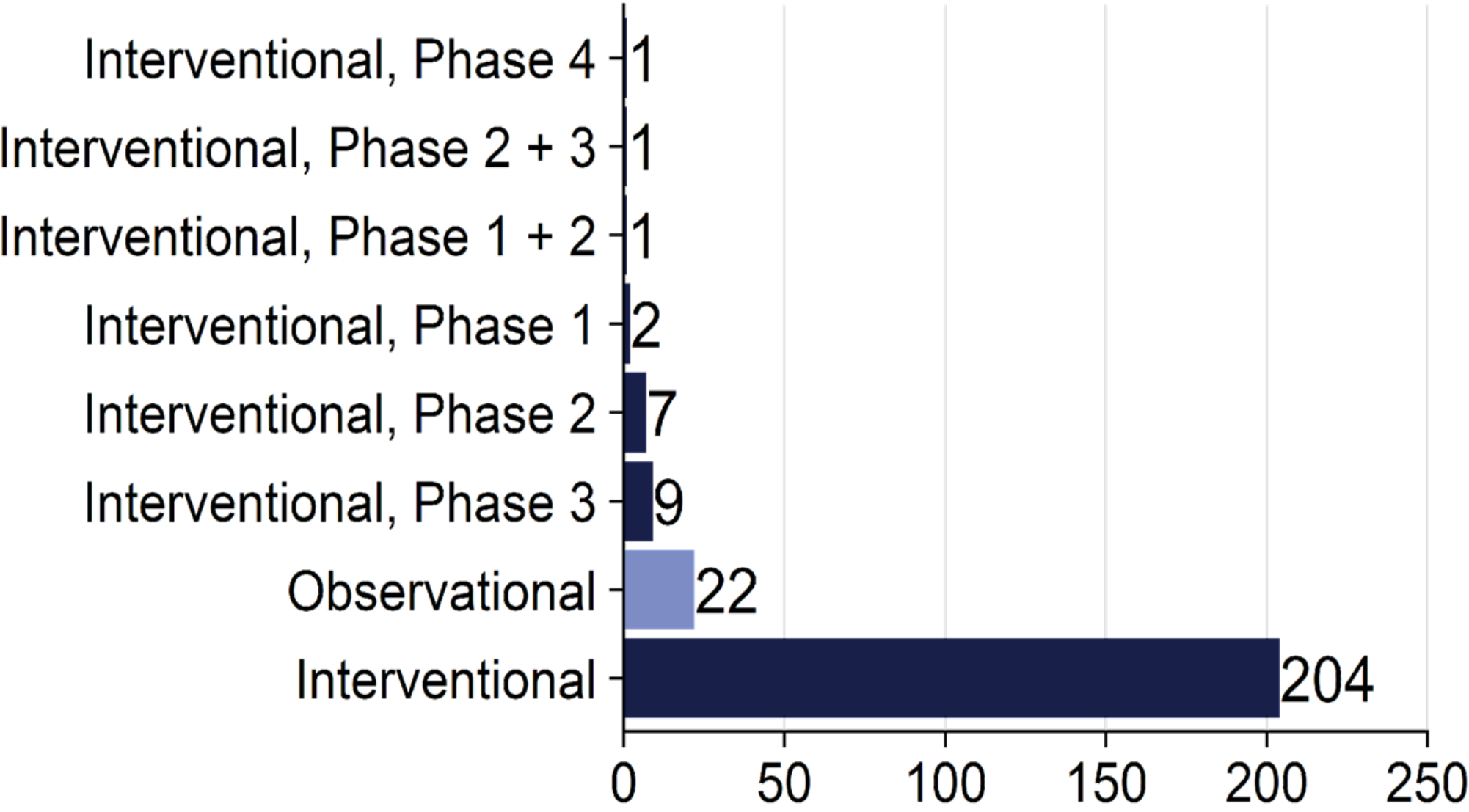
Fig 1: Number of GAS Trials by Start Year



Most of the trials utilizing GAS were interventional (91%).

Of the 21 interventional trials with phases listed, most were phase III 9 (43%), 7 (33%) were phase II, 2 (10%) were phase I, and others were one phase IV and combined trials.

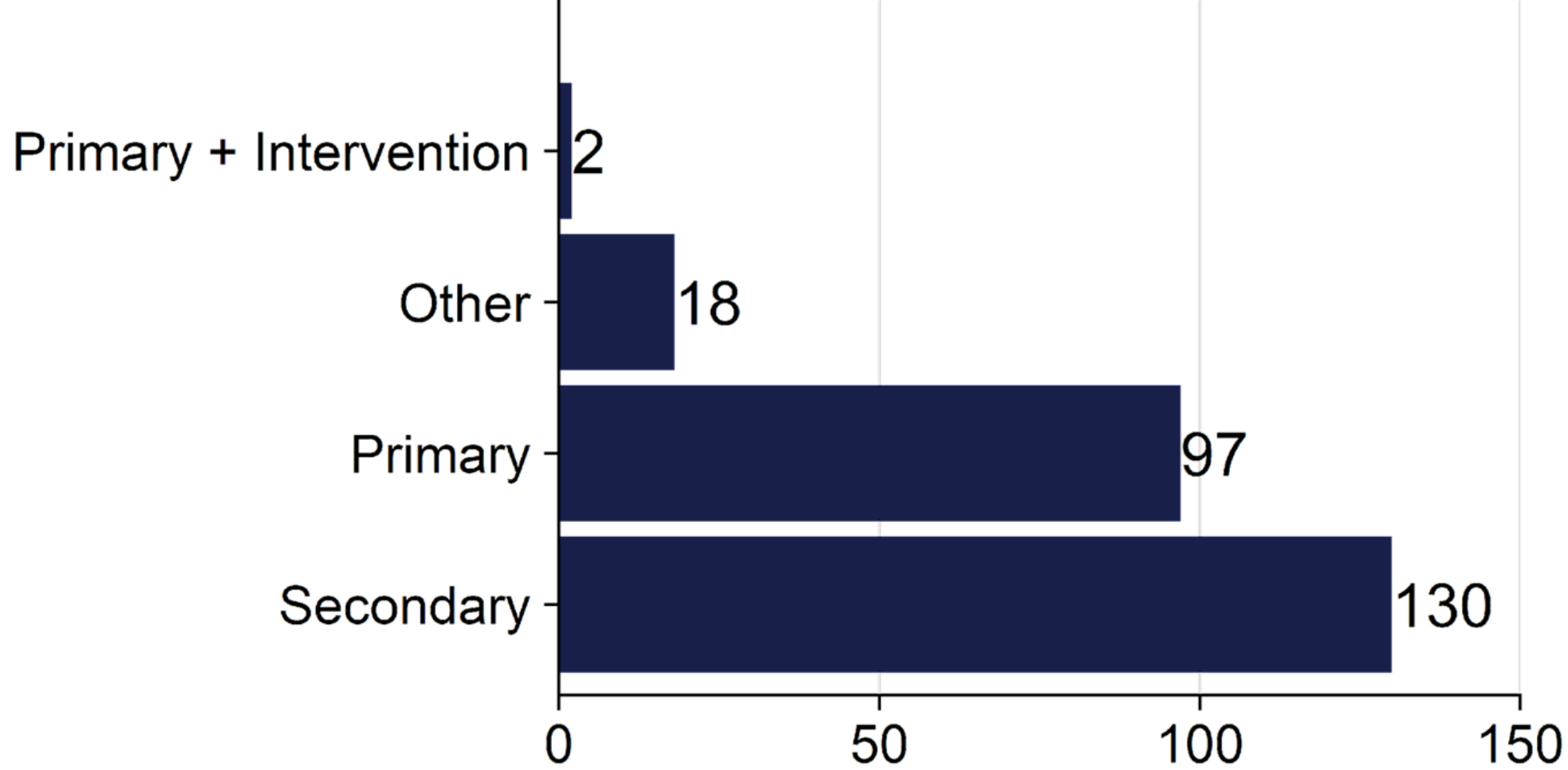
Fig 2: Number of GAS Trials by Type and Phase



GAS was the primary outcome in 40% of the trials, secondary in 53%, and 'other' in 7%.

In 1% of the trials, GAS was also part of the intervention.

Fig 3: Number of Trials by GAS Application



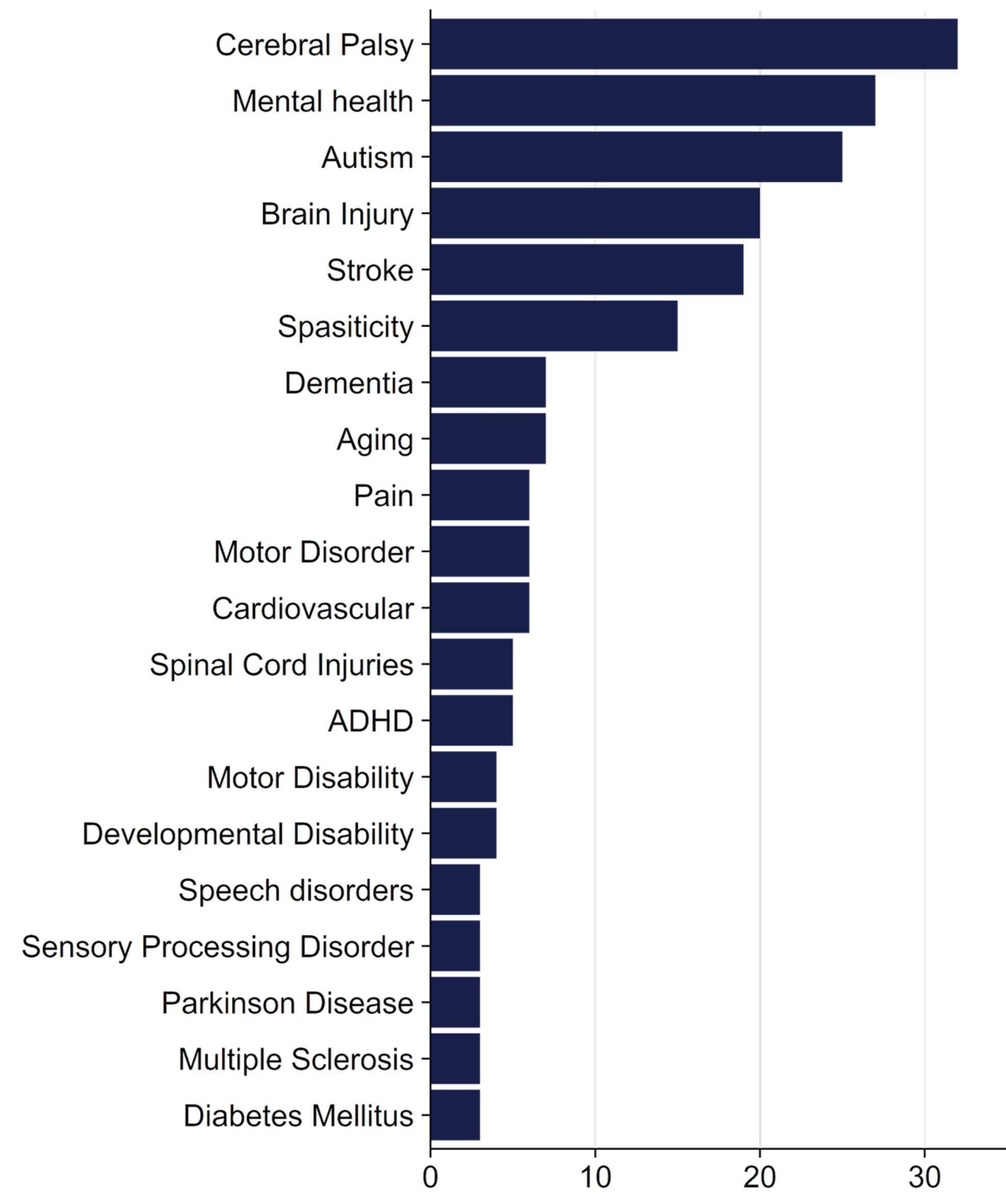
Methods

- A search for the terms "goal attainment scale" and "goal attainment scaling" was conducted on clinicaltrials.gov for trials from 2014-01-01 to 2023-12-18.
- Trials that were terminated, suspended, or withdrawn were excluded.
- Each of the trials were reviewed to analyze GAS implementation and summarized.
- Trials were summarized based on the trial type and trial phase.
- Disease and conditions were consolidated with umbrella terms for consistent naming.

Results

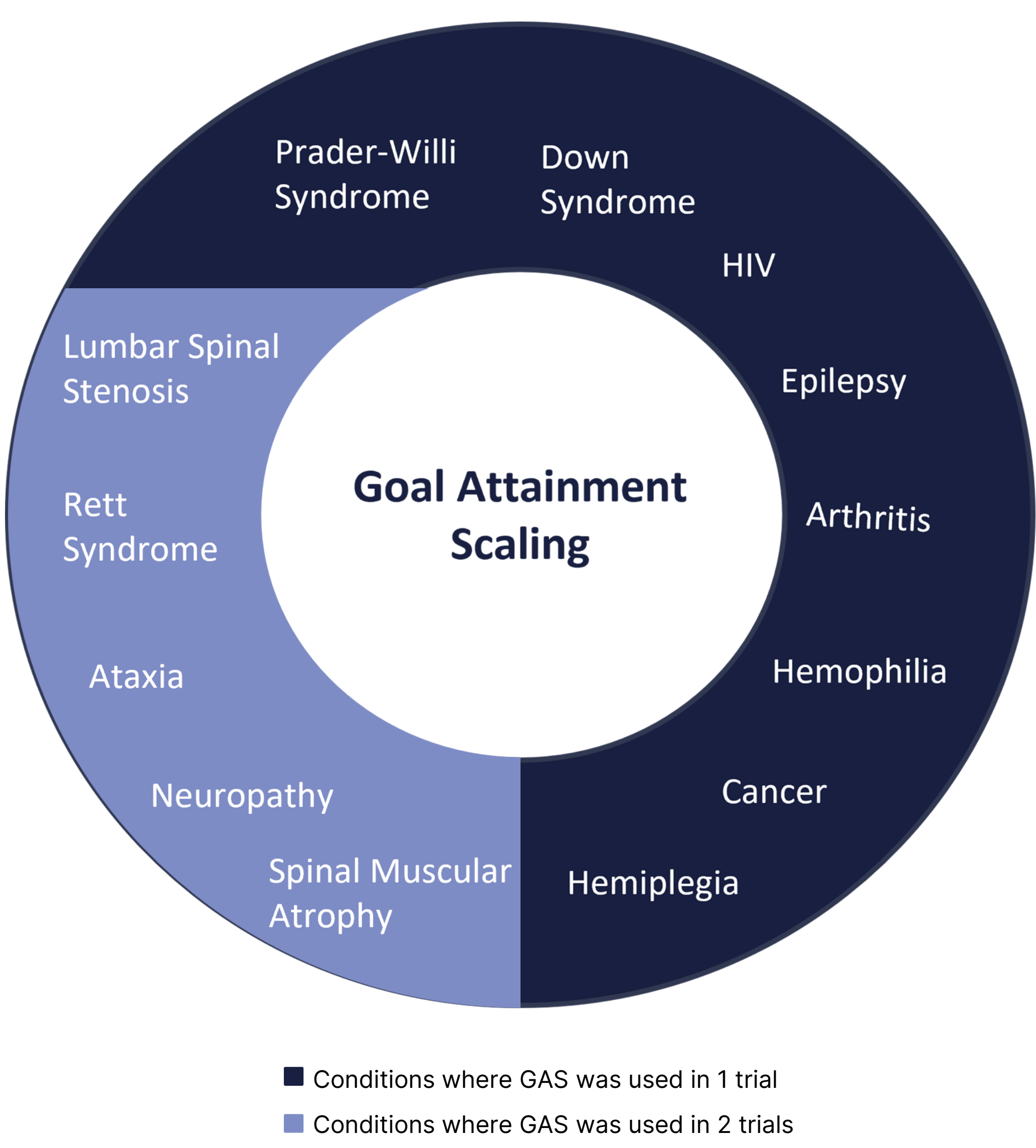
GAS was most often used in Cerebral Palsy (32, 13% of trials), Mental Health (27, 11%), Autism (25, 10%), Stroke (19, 8%) and Spasticity (15, 6%).

Fig 4: GAS application by condition



Novel uses of GAS were identified in several rare diseases (e.g. Rett Syndrome, Prader-Willi Syndrome).

Fig 5: Examples of novel uses of GAS in clinical trials



Discussion & Conclusion

Interest in GAS has increased over the last decade across multiple disciplines.

Most studies that employed GAS were interventional, where it was used as a primary or secondary outcome.

GAS acceptability is broad, as illustrated by its use in various conditions and novel uses in rare diseases.

Interest in GAS is likely to increase further with the FDA's mention of personalized endpoints in draft patient-focused drug development guidance 4.²

Acknowledgements & References

¹Kiresuk, T. J., & Sherman, R. E. (1968). Goal attainment scaling: A general method for evaluating comprehensive community mental health programs. *Community mental health journal*, 4, 443-453.

² <https://www.fda.gov/drugs/development-approval-process-drugs/fda-patient-focused-drug-development-guidance-series-enhancing-incorporation-patients-voice-medical>