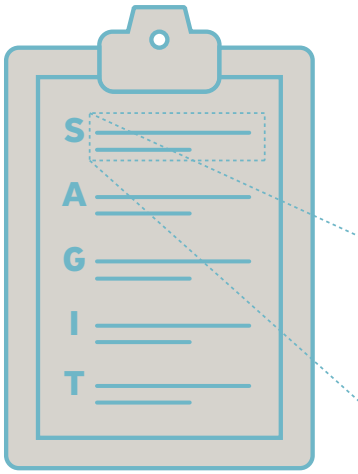
Giustina A et al. *J Clin Endocrinol Metab 2021; Epub ahead of print*

International Multicenter Validation Study of the SAGIT® Instrument in Acromegaly

What is SAGIT and how can it be used?

SAGIT is an instrument to help standardize classification of acromegaly through disease activity scoring across 5 items:



Click to access the complete SAGIT® instrument

S	A	G	I	T
Signs and symptoms	Associated comorbidities	Growth hormone concentration	Insulin-like growth factor 1 concentration	Tumor size
Score range: 0–4	**Score range: 0–6**	**Score range: 0–4**	**Score range: 0–3**	**Score range: 0–5**

Which of the symptoms (S) from the list below is your patient experiencing?

Headaches ☐ Sweating ☐ Joint symptoms ☐ Swelling ☐

Sum up the number of symptoms (S) ticked **S = ...**

Higher scores represent increased disease severity

Why was SAGIT developed?

SAGIT has been developed to address the unmet need for a global reference instrument to:

- better characterize acromegaly disease activity
- provide a precise classification of disease severity
- evaluate the response to treatment

Why use SAGIT in clinical practice?

To improve and standardize the application of current guidelines and support objective treatment guidance

To provide information to help doctors decide how to treat and manage acromegaly

How was SAGIT developed?

Pilot phase
Designed by a steering committee of acromegaly experts

2013–2014

Pre-testing:
Use of medical records

2013

Pilot study: Testing in clinical practice

2014

Publication of SAGIT pilot study results
SAGIT®: clinician-reported outcome instrument for managing acromegaly in clinical practice—development and results from a pilot study. Pituitary[1]

2016

Validation phase
Multicenter, non-interventional study to evaluate the ability of SAGIT to discriminate between acromegaly disease control status and define acromegaly staging

2015–2018

Publication of baseline data from the SAGIT validation study
Staging and managing patients with acromegaly in clinical practice: baseline data from the SAGIT® validation study. Pituitary[2]

2019

Publication of completed SAGIT validation study
International Multicenter Validation Study of the SAGIT® Instrument in Acromegaly. J Clin Endocrinol Metab.[3]

2021

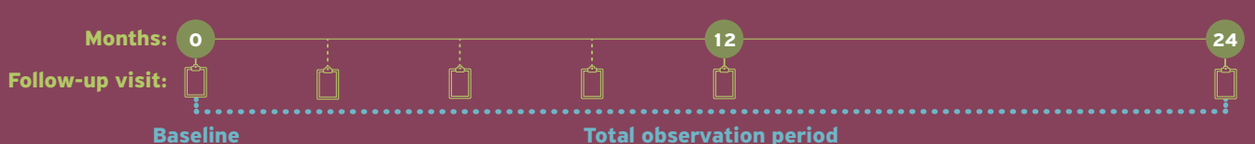
Roll out of SAGIT in clinical practice

Real-world evidence generation

Ongoing

Validation study design

Primary objective: Determine the ability of SAGIT to accurately discriminate between patients with controlled and uncontrolled acromegaly



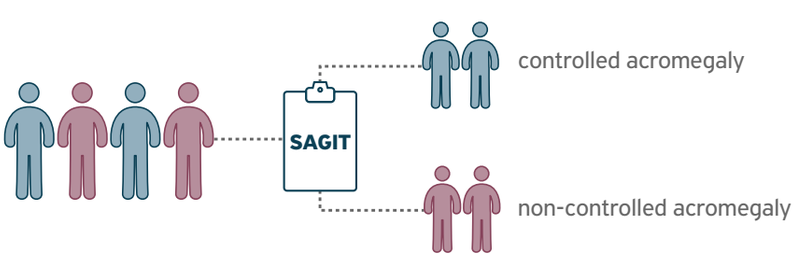
227 patients were enrolled

24 study sites

Assessed at each visit:
- SAGIT score
- Subjective and objective evaluation of disease control
- Evaluation of disease control based on international guidelines
- Quality of life

Results: SAGIT has been validated for use in clinical practice

- SAGIT exhibited optimal accuracy when predicting the clinical global evaluation of disease control (subjective)
- Results were consistent with classifications by international guidelines to define acromegaly disease control,[4,5] and consistent with the investigator's therapeutic decision (objective)



References

1. Giustina A, et al. SAGIT®: clinician-reported outcome instrument for managing acromegaly in clinical practice-development and results from a pilot study. Pituitary. 2016;19(1):39–49. **2.** Giustina A, et al. Staging and managing patients with acromegaly in clinical practice: baseline data from the SAGIT® validation study. Pituitary. 2019;22(5):476–487. **3.** Giustina A, et al. J Clin Endocrinol Metab 2021; Epub ahead of print. **4.** Giustina A, et al. A consensus on criteria for cure of acromegaly. *J Clin Endocrinol Metab.* 2010;95(7):3141–3148. **5.** Giustina A, et al. Expert consensus document: A consensus on the medical treatment of acromegaly. *Nat Rev Endocrinol.* 2014;10(4):243–248.