

Value of novel digital endpoints in late-stage trials



About AbbVie

[AbbVie](#) is a global pharmaceutical company whose mission is to discover and deliver innovative medicines and solutions that address complex health issues and enhance people's lives.



The opportunity

- Many dermatological conditions can severely impact a person's quality of life.
- Current gold standards for measuring the severity of various dermatological conditions often introduce subjectivity and placebo effect with varying levels of inter-rater reliability.



The challenge

- AbbVie sought a better outcome measure to precisely quantify condition severity and drug efficacy. The asset teams investigated if a technology could fill this need.
- The technology landscape at the time did not offer a validated product that AbbVie could immediately deploy into global trials.



The approach

- AbbVie identified a technology partner with a promising imaging product that can objectively measure changes in dermatological conditions. AbbVie collaborated with the technology partner to clinically validate its algorithms and scale its operations to support global trials.
- With support from the technology partner, AbbVie presented the validation results to the FDA to gain the agency's acceptance of utilizing this novel digital measure as a ranked endpoint in clinical trials.



The impact

- ✓ The FDA agreed with AbbVie's approach for utilizing an objective digital measure as a ranked endpoint in Phase 3 clinical trials.
- ✓ Clinical trials utilizing traditional endpoints often require hundreds of patients. Deploying this objective measure, AbbVie powered a clinical trial with a threefold smaller patient size to demonstrate differentiating evidence.
- ✓ For the next generation of therapy, AbbVie could potentially use this validated endpoint as a primary endpoint, saving significant time and cost.
- ✓ A picture is worth a thousand words! This imaging digital measure could be more relatable to patients, allowing healthcare providers to describe potential treatment benefits better.

“Digital health technology offers a transformative path to drug development by providing objective, sensitive, and meaningful endpoints. We look forward to seeing DiMe's Business Case project provide the industry a solid framework of value analysis and drive adoption.”

— **Michelle Crouthamel**

Head of Digital Science, AbbVie

This case study was based on data gathered from the following study: [A Study To Assess Adverse Events and Effectiveness of Upadacitinib Oral Tablets in Adult and Adolescent Participants With Vitiligo \(Viti-Up\)](#).

