

Innovative Solution to Gathering Real-World Data from Patients and Clinicians

Agnostic Platform Combines Applications, Integrates Results

When one top-tier pharmaceutical company sought to better understand the patient journey in a rare dermatological condition that was difficult to diagnose, the company's Medical Affairs team turned to Emmes for help in designing a prospective observational study. The innovative Emmes solution gathers multiple perspectives through different applications integrating data via one platform for a comprehensive, unified view of each patient's experience with the healthcare system.

The Challenge: Lack of Insight into Patients' Diagnosis and Care Journey

Patients with a particular rare dermatological disease are often not diagnosed correctly for years – an average of 10 years after onset of their symptoms – and so consequently endure a prolonged period with a reduced quality of life. Emmes's long-standing client wished to better understand patients' journey through the healthcare system in order to improve their care.

The Sponsor provided Emmes with a synopsis of the study plan and asked for help in developing the research protocol aimed at enrolling several hundred diagnosed patients in one country. The request was challenging in that:

- The solution would involve collecting data from clinicians and directly from patients using multiple tools and applications.
- Each patient's information had to be gathered in a certain sequence during patient visits.
- Privacy protections would have to extend across all data sources, while allowing for integration. Additionally, one of the tools was a closed, off-the-shelf system that could not be altered to prevent the entry of personally identifiable information.
- Patients' informed consent would need to be granted separately for the off-the-shelf tool.
- As the data would be collected during dermatology clinic visits, an online connection would need to be ensured for each site.

The Emmes Solution: A Single Interface across Data Collection Tools, Technology Vendors

A cross-functional team at Emmes worked collaboratively with the Sponsor's Medical Affairs team to design a protocol and implement an approach that allowed for a seamless experience during clinic visits, ensured patient privacy, and integrated data from multiple tools.

The solution incorporates three applications in one landing page on a tablet to be used during patient visits: a medical history completed by the patient, the electronic Case Report Form (eCRF) completed by the clinician, and a diagnostic tool used by the patient to report on symptoms. The links on the landing page are both role-based and presented in a guided mode to ensure use in the proper sequence. (The guided mode can be exited if necessary to set up the site-specific WLAN, but must be restored before the tablet is handed over to a patient.)

The Emmes team built step-by-step guidance into the interface so that patients could easily follow the protocol and would provide their separate consent for each data collection tool. Emmes also used the site initiation visits to educate the site staff around the workflow, since it is so novel.



Extra privacy protection measures were put in place to scrub the database of any personally-identifiable information that could be inadvertently entered in the off-the-shelf tool.

Emmes data managers worked across systems so that the data from three different applications were uploaded automatically to the cloud and integrated into a single view.

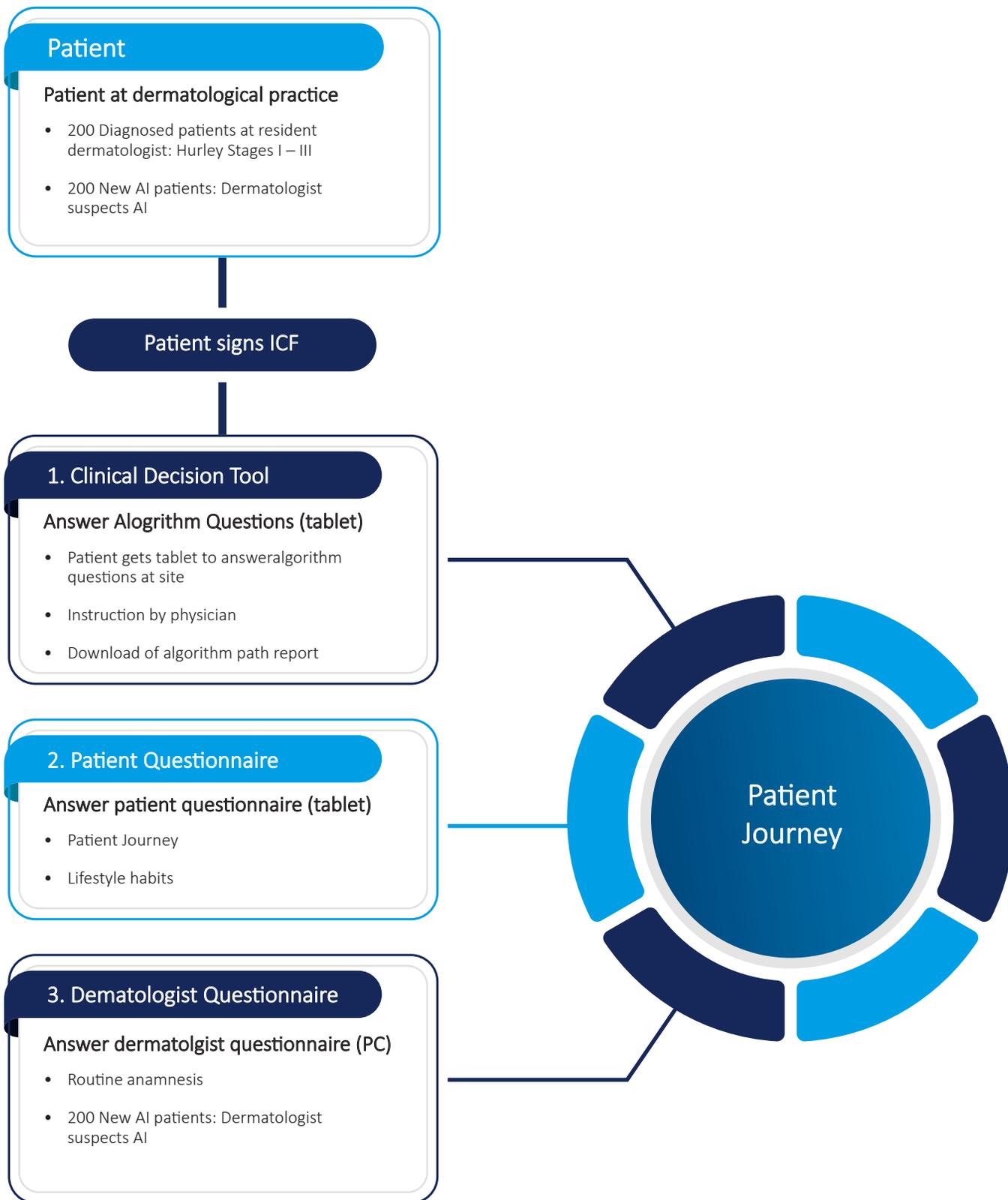
The Results: Comprehensive, Longitudinal Data from Multiple Sources

Emmes project and data managers coordinated the system development across vendors to support a timely and smooth implementation of the study, which is currently underway. The novelty of the approach necessarily involved some scope creep and the need to adjust to unforeseen circumstances as the project progressed. Emmes, to keep the project on schedule, addressed issues proactively and continued pursuing the project goals, even when it meant performing some work at risk.

The Sponsor, in turn, impressed with the team's flexibility, professionalism, and "can-do" attitude, has committed to working with Emmes on a follow-on study.

The Sponsor's feedback has emphasized their appreciation for the team's "fantastic support" and "trusted collaboration" which has led to an excellent outcome.

TeleVersal/AI Patient Characterization



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