RESULTWORKS
Transforming Strategy. Delivering Success.

Integrating mHealth Digital Devices into Clinical Trials

THE SITUATION

Many pharmaceutical companies are increasingly focused on developing strategies that will enable them to realize the benefits of using mobile health and digital biomarker data collection technology on clinical trials. Sponsors are challenged to keep pace with the rate of change amidst the rapid emergence of new devices, solutions, and vendors, to understand what capabilities exist, and to implement those capabilities in an effective, efficient, and compliant manner.

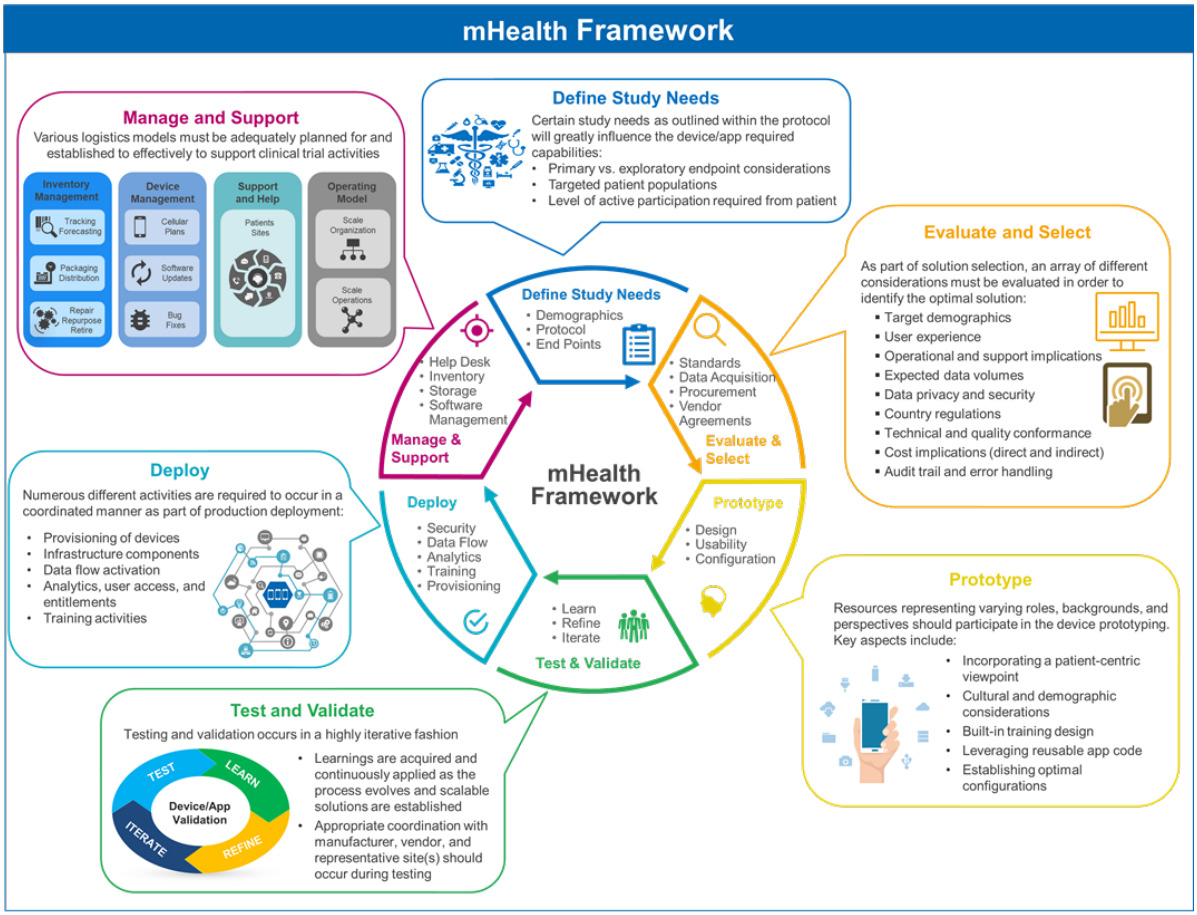
One global pharmaceutical organization had increasing demands by study teams to use devices and mobile applications in the conduct of clinical trials for improved patient engagement, faster data acquisition and access, and higher quality data. Pilot initiatives resulted in cumbersome, resource-intensive, and time-consuming processes with point solutions to support such devices and applications.

As pilot initiatives progressed, it became evident that a comprehensive, long term strategy was needed to address concerns about scalability, vendor assessments, specification and deployment of solutions, and data privacy among other concerns.

THE SOLUTION

ResultWorks assessed the current client environment and conducted an external industry benchmark to understand the landscape across the industry. An mHealth framework was developed to capture the findings and challenges across a number of high-level categories including:

- The selection, usability, provisioning, and ongoing management of devices
- Data capture, quality, storage, and analysis
- Ongoing support and training with regards to internal teams, patients, and sites
- Security and privacy



A few key takeaways from the industry benchmark survey included:

- The mobile health adoption rate is still relatively low across the industry – most sponsors are still in the early stages of evaluating and testing devices and processes
- The technology landscape is evolving quickly with many new devices and services vendors
- Regulatory interpretations are also evolving with regards to data, security, and privacy
- Leading sponsors have formed dedicated, multidisciplinary teams to evaluate and pilot devices and software vendors to determine the scientific, business, and technology fit

Utilizing the mHealth framework, ResultWorks facilitated a series of ResultSessions[SM] to establish the future state strategy. The future state strategy outlines the IT capabilities, technology architecture, business processes, and resources needed to best support the study teams in their

use of digital biomarker collection devices, while building toward the establishment of qualified supported capabilities and corresponding support models.

Once the future state strategy was refined and aligned, additional working sessions were conducted to construct the sequenced, multi-year roadmap to realize the strategy.

KEY BENEFITS

Strategic Business Models: Established business models to deliver high-quality solutions at optimal efficiency by developing and streamlining repeatable processes for efficiency and scale.

Flexible Approach: A flexible, iterative approach enables innovation and experimentation in which learnings are acquired as the process evolves while key enterprise capabilities are built out and enterprise scale is achieved.

Comprehensive Roadmap: Developed a comprehensive roadmap for implementation including prioritization, timing, and sequencing for key dependent activities that can be easily adjusted and refined as the strategy evolves.

> "I really liked the pace. I've seen other strategy projects drag on for 6 months, but this project was more appropriate. The deliverables are manageable and can be adjusted easily as we learn more."
>
> - Clinical Innovation Lead

For more information, visit our website www.resultworksllc.com or contact us at marketing@resultworksllc.com.