

Clinical Trial Patient Engagement Products Trailblazer Assessment 2024

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Glossary

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Introduction and overview

Research methodology

Background of the research



Background of the research

In the dynamic field of life sciences clinical development, patient engagement has emerged as a critical driver of innovation and success. As clinical research evolves, integrating patient perspectives and active participation has become a transformative force, significantly enhancing the quality and relevance of clinical trials.

This report delves into the pivotal role of patient engagement within the context of clinical development, underscoring its importance in shaping the future of medical research and treatment. Effective patient engagement throughout the clinical trial process, from study design and recruitment to data collection and dissemination of results, ensures that trials are more patient-centric, efficient, and likely to yield meaningful insights.

Patient engagement in clinical development is not merely a regulatory requirement but a strategic imperative. Patients who are engaged are more likely to participate in clinical trials and remain committed throughout the study, thereby reducing dropout rates and accelerating the research timeline. By involving patients in the design and conduct of trials, researchers can collect more relevant data that better reflects real-world experiences and outcomes.

Transparent communication and active involvement of patients foster trust and build stronger relationships between researchers, sponsors, and patient communities. Furthermore, trials designed with patient input are more likely to meet regulatory expectations and produce results that are highly valued by healthcare providers and patients, facilitating smoother market access.

This report will explore practical strategies for incorporating patient engagement into clinical development, from leveraging digital tools and platforms to creating patient advisory boards and using patient-reported outcomes. We will also examine case studies and best practices that illustrate the tangible benefits of patient-centric approaches.

In the quest to develop new therapies and treatments, the voice of the patient is indispensable. Embracing a patient-centered paradigm drives more effective, ethical, and responsive clinical research, ultimately leading to breakthroughs that significantly improve patient lives. This report aims to illustrate how we can transform clinical development through the power of patient engagement, paving the way for a more inclusive and impactful future in life sciences.

Scope of this report

Geography: global

Industry: life sciences

Services: patient engagement

Use cases: 6 leading start-ups in the

patient engagement industry

Patient engagement – market overview

Defining patient engagement

Features of patient engagement platforms

Drivers and barriers to adopting patient engagement platforms



Everest Group's view of patient engagement products capabilities

Scope of assessmen

Patient onboarding

- Automated patient forms (Auto-populating patient data)
- Interactive content (pre-engagement)
- Appointment scheduling (visit schedules, visit information)
- Patient payment support

Patient communication and education

- Multimedia content for patient education
- Gamified personalized progress meter
- Automated task lists
- Downloadable reports for various modules and health information

Patient adherence

- Reminders and notifications through application alerts
- Information on pharmacies and care coordinators (Home nursing)
- Adherence reports indicating patient compliance

Patient feedback

- Incorporating patient feedback through interactive surveys
- Ticket generation & guery resolution mechanism (Chatbots, and other support channels)
- Redressal report showcasing patient satisfaction levels

Multilingual functionalities

Platform/product modules

Patient data capture

Analytics & reporting

Patient retention & Patient engagement analytics dropout analytics

Key risk indicators, quality tolerance limits Dashboard showcasing patient journey

Business intelligence

Data governance, privacy, and security

Data Compliance (HIPPA, Backup and Audit and User access GDPR, ISO, CDISC, etc.) Authentication traceability encryption management recovery

Note: The platform modules included in the scope of the research provide an indicative list of features and functionalities to be considered during the evaluation of the platform. While there may not be a single solution offering all these capabilities, they can be integrated across different products in the overall platform



Features of patient engagement platforms

Patient engagement platforms ease the clinician's burden in managing patients and enhance patient experience in clinical trials through multi-faceted engagement tools

"This collaboration will enhance our efforts to connect and engage patients and investigators as we continue on our mission to decentralize clinical trials and extend these life-changing opportunities to more patients across the world."

- Global Head of Clinical Sciences and Operations, a leading life sciences company



On-demand access to patient training and education modules



Mobile and web applications to facilitate patient communication, visit scheduling, etc.



Al-based analytics dashboards for sites to monitor enrollment, engagement, and ePRO compliance, with customizable notifications to identify lapses in compliance



Personalized content such as configurable avatars, delivery of reminders, study material, motivational content, etc.



Ability to set up protocol scheduling for automatic reminders, alerts, and notifications to all patients across sites



Remote monitoring and patient data collection through eCOA and ePRO



Multilingual helpdesk to solve patient queries through Al-based virtual assistants and clinician staff



Integrated, in-app telehealth systems for simultaneous data capture and review

Myths busted: Gamification in patient engagement is about creating the standard instruments as video games!



Gamification is not allowed in patient engagement!





- Gamification is not about playing a video game; it is about leveraging the elements commonly found in games to enhance user experience and drive compliance in completing questionnaires and tasks
- Dropouts in clinical trials often occur due to patients' reluctance to take medications, lack of belief in the treatment process, or feelings of disengagement and disconnect. Gamification addresses these challenges by providing a more engaging and interactive experience for patients, ultimately improving their adherence to the treatment plans
- Regulatory bodies acknowledge the potential benefits of gamification but emphasize the importance of validating these methods and instruments and obtaining Institutional Review Board (IRB) approvals before implementing any changes to processes related to patient engagement

Drivers and barriers to adopting patient engagement platforms

Improving study performance and retention and elevating participant experience are the top drivers for adopting patient engagement platforms while regulatory requirements and data privacy concerns continue to be major headwinds

Drivers to patient engagement platforms



Improving overall clinical study retention



Enhancing patient adherence



Enhanced UI/UX capabilities



Omnichannel engagement capabilities



Advanced data analytics to improve study performance



Reduced burden on clinical trial site staff

Barriers to patient engagement platforms



Lack of an all-in-one feature platform



Addressing local regulatory requirements



Patient data and privacy concerns



Patients' limited digital literacy



Demonstrating Rol and the value of Patient Engagement (PE) initiatives



Keeping up with the evolving consumer demands

Differentiated capabilities by identified trailblazers

Gamification, behavioral science, and Al-based capabilities stand out in the identified trailblazers as they look to leverage emerging technologies and deliver a hyper-personalized patient experience



Gamification and behavioral science

- Platform providers have developed gamified content repositories designed to train and educate the participants of clinical trials. These repositories are readily accessible through in-app menus, allowing participants to engage with the content on-demand and remotely at their convenience
- Leveraging behavioral science, platform providers are designing personalized content to engage participants such as configurable avatars, in-app rewards for task completions, timely reminders, study details, and motivational content. As a result, sites are able to improve questionnaire compliance, visit adherence, medication adherence, and overall study retention



Al and ML-enabled modules

- Platform providers have integrated Al and ML into their platforms to analyze in-app behavior and deliver auto-generated personalized notifications/reminders to participants
- They have implemented data analytics capabilities to allow study staff to view and monitor real-time dashboards in order to identify and respond to any lapses by participants
- They are integrating generative AI within their platforms to develop personalized content for participants to enhance user experience and improve adherence and retention rates
- Additionally, by leveraging AI, platforms enable patients to find and engage with similar participants for a hyper-personalized experience



Multilingual capabilities

- Platforms have launched in-app features to enable language translations in multiple languages in order to enable broader access for CROs to identify participants
- Further, platforms have launched help desks for catering to participants in multiple local languages to promote accessibility and inclusivity

Assessment of patient engagement trailblazers in the market

Assessment methodology

High-potential start-ups in the patient engagement market

Patient engagement trailblazers - leaderboard

Patient engagement trailblazers - profiles



Everest Group analyzed 44 start-ups on key dimensions to shortlist the top six trailblazers in the patient engagement market

Approach for prioritizing start-ups

The initial data of 44 start-ups was collected based on market interactions and the existing research.

A comprehensive evaluation was done to identify the highpotential start-ups that were providing patient engagement solutions. These start-ups were evaluated based on the extent of their domain-focused offerings, market traction, core competencies, technology and innovation, talent, and leadership.

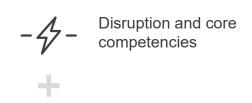
A further assessment of the high-potential start-ups led to the identification of trailblazers in the patient engagement market.

These start-ups play a significant role in providing patient engagement software/services/solutions.



Dimensions used for prioritizing start-ups Domain focus and coverage







We assessed the start-ups based on their domain focus, market buzz, technology, and human capital



- Does the start-up have significant experience in serving the patient engagement market and is it a patient engagement dedicated firm?
- Are the start-up's offerings in line with the current trends in the patient engagement industry?
- What is the start-up's vision, and does the strategy it adopts align with the current industry requirements?



- How is the investor confidence?
- What is the start-up's client mix?
 Does it have a diverse mix of clients in the life sciences industry?
- What kinds of awards and recognitions has the start-up received?



- To what extent has the start-up created new/innovative solutions or software offerings in the patient engagement market?
- What is the impact of the solution provided?
- How technologically sophisticated is the solution?
- What is the start-up's partnership ecosystem?



- How large and geographically diverse is the workforce?
- How strong and relevant is the leadership cohort (in terms of patient engagement and from a technology experience standpoint)?
- What are the start-up's recent hiring trends?

After a detailed assessment of 44 start-ups, 30 emerged as having high potential





























































Based on the assessment framework and after an in-depth dimensional analysis, we identified six of the shortlisted 30 high-potential start-ups as trailblazers



Six start-ups identified as trailblazers





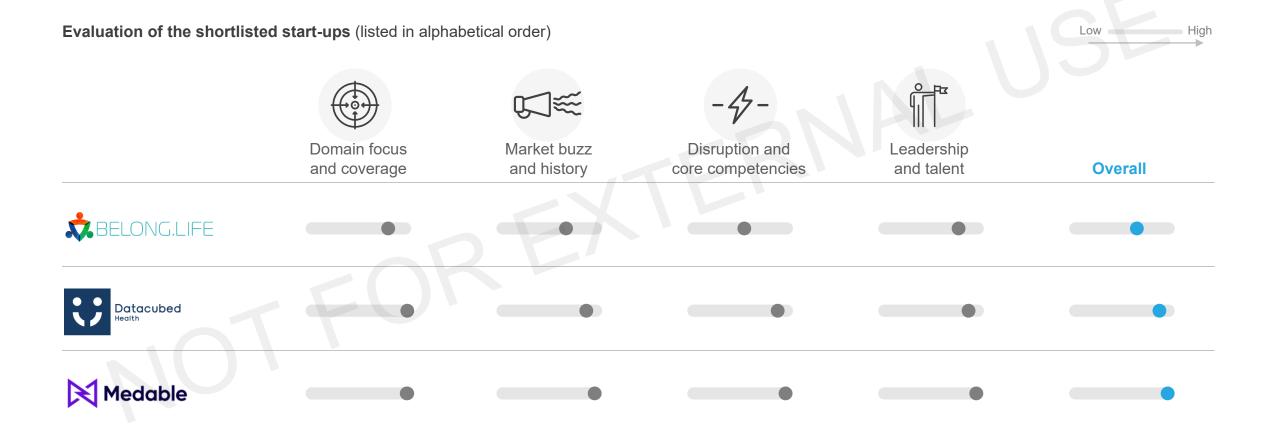








Patient engagement trailblazers – leaderboard (page 1 of 2)



Note: All the ratings are relative to the shortlisted trailblazers Source: Everest Group (2024)



Patient engagement trailblazers – leaderboard (page 2 of 2)

Evaluation of the shortlisted start-ups (listed in alphabetical order) Domain focus Market buzz Disruption and Leadership and history core competencies and talent and coverage Overall **(ripple** THREAD **Y**Prime

Note: All the ratings are relative to the shortlisted trailblazers Source: Everest Group (2024)



Belong.life

Provides a platform that aims to contribute to improved healthcare outcomes globally by utilizing AI to proactively support patients throughout their healthcare journeys and by offering research and access to relevant clinical trials

Company overview

- Belong.life is a social and professional patient engagement and treatment management platform that uses conversational AI, big data, and active patient communities to offer engagement, Real-World Evidence (RWE), patient research, and clinical trial matching services
- Belong.life's key offerings include social and professional networks for cancer patients (Belong – Beating Cancer Together) and Multiple Sclerosis (Belong MS).
 Additional offerings include real-time conversational AI health mentors: Dave for cancer, Sophie for MS, and Tara – an AI clinical trials matching assistant that helps gather relevant patient data to find personalized trial matches for patients

Fact sheet

Year of incorporation 2	2014
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Key executives

- Eliran Malki, Chief Executive Officer and Co-Founder
- Irad Deutsch, Chief Technology Officer and Co-Founder
- Ohad Rubin, Chief Financial Officer, Chief Operating Officer and Co-Founder

Headquarters

New York, New York

Number of employees 51-200

Investor confidence – estimated total funding of US\$40 million

Domain focus	*	*	*	*	\Rightarrow
Market buzz and history	*	*	*	*	\Rightarrow
Disruption and core competencies	*	*	*	$\stackrel{\wedge}{\sim}$	\Rightarrow
Leadership and talent	*	*	*	*	\Rightarrow
Overall	*	*	*	*	\Rightarrow

Patient engagement offerings

- Belong Al Dave: this Cancer Mentor App leverages Belong's proprietary conversational Al technology to provide personalized patient support. Features include public community engagement/support, a personalized Al assistant, and clinical trial matching
- Belong Cancer and Belong MS: a social and professional network for people living with cancer and MS, providing a space for patients to connect and access professional support
- Tara for clinical trial matching: leverages Machine Learning (ML) technology and Natural Language Processing (NLP) algorithms to recruit relevant patients for clinical trials
- SaaS-based patient Engagement platform: high engagement solutions with hyper-personalized and configurable patient engagement tools (PROs, RWE, auto-care coordination, and reminders), navigation tools, and management services

Partnerships

Partnered with providers, consulting firms, and hi-tech enterprises such as AWS, Ernst & Young, Bayer, Astra Zeneca, Sheba Medical Center, Janssen, IQVIA, and GQ2

Recognition and awards

Medtech Visionaries Awards 2021, Health Tech Digital Awards 2020, recognized by Newsweek and Montreal Oncology



Datacubed Health

Offers patient engagement, ePRO, and eCOA with extended decentralized clinical trial capabilities; aims to advance access to healthcare for all by incorporating behavioral science and data analytics

Company overview

- Datacubed Health, an eClinical technology company, is focused on creating better clinical trial experiences for patients, sites, and sponsors by offering solutions that are layered with behavioral science, improving retention and compliance.
- Datacubed Health offerings include a Decentralized Trials Platform, eCOA/ePRO, patient engagement, eConsent, medication adherence, and televisits.

Fact sheet

Year of incorporation	2016
Key executives	 Kyle Hogan, Chief Executive Officer Vikram Nataranjan, Chief Technology Officer Kim Williams, Vice President of Solution Design Nathaniel Greer, Vice President of Compliance Alex Mcsherry, Vice President, Global Business Development
Headquarters	King of Prussia, Pennsylvania
Number of employees	51-200
Investor confidence -	estimated total funding of US\$44 million

Domain focus	* * * *	*
Market buzz and history	* * * *	*
Disruption and core competencies	* * * *	*
Leadership and talent	* * * *	*
Overall	* * * *	*

Patient engagement offerings

Datacubed Health offers a DCT platform with solutions such as:

- Patient Engagement a behavioral science-based digital health enablement solution providing clinical trial information, reminders, support, and motivation with optional gamification at critical timepoints, where patients need support the most
- eCOA/ePRO a patient and clinician software solution designed to collect the outcome measures required by protocol with enhanced capability for digital study by study specificity
- eConsent a built-in Electronic Consent that facilitates a consent process for patients and caregivers both at the research facility and remotely
- Medication Adherence helps patients enter critical details about study drug administration for clinical trial monitoring and alerts thus offering better patient support and results
- Televisits offers virtual visits built into the app that enables decentralized trials and improved participant experiences

Partnerships

Partnered with multiple service providers and hi-tech enterprises such as Amazon Web Services (AWS), The Rocket Science Group, Stefanini Group, Twilio, and Splunk

Medable

Offers a digital platform that enables clinical trial sponsors to collect data and generate evidence to answer scientific questions

Company overview

- Medable is a SaaS technology platform focused on the evidence generation needs of drug development programs from target product profile to submission ready data
- It is built from the ground up to focus on data acquisition and evidence collection directly from patients in consumer-grade experiences and is designed to fit within the site workflows
- Medable serves life sciences companies such as GSK, Nova Scotia Health Innovation Hub, and Syneos Health

Fact sheet

Year of incorporation 2016

Key executives	 Michelle Longmire, Chief Executive Officer and Co-founder Tim Smith, Co-founder and Chief Technology Officer Amar Jani, Chief Financial Officer Pamela Tenaerts, Chief Scientific Officer Hady Khoury, Chief Development Officer
Headquarters	Palo Alto, California
Number of employees	251-500

Investor confidence – estimated total funding of US\$507 million

Domain focus			*		
Market buzz and history	*	*	*	*	*
Disruption and core competencies	*	*	*	*	*
Leadership and talent	*	*	*	*	*
Overall	*	*	*	*	*

Patient engagement offerings

Medable Studio, an all-in-one application for configuring, translating, validating, and launching eCOA+ (eCOA, eConsent, Televisit, Sensors) into clinical trials.

- eCOA+ enables the collection of PROs, ClinROs, and ObsROs via electronic devices, enabling real-time data capture, and supporting remote monitoring, integration with digital health devices, and customizable workflows
- Total Consent facilitates electronic capture of informed consent, simplifying patient review, and digital signing
 of consent forms
- Therapeutic Area Aligned Digital Strategies is a program-level approach of consulting and designing best
 practices with lived patient experiences. Examples include Medable's oncology offering which facilitates data
 collection for sites and sponsors and Medable's vaccine offering that enables better site and patient experiences
- Patient Caregiver Network (PCN) gathers real-time insights on participant preferences and experiences from global patient and caregiver advocates, helping shape Medable's strategy, products, and support for clients

Recognition and awards

2024 Best Digital Health Solution UK Prix Galien for Medable Evidence Generation Platform

2023 Best Digital Health Solution USA Prix Galien

2022 Most Valuable Clinical Technology Award at Reuters Pharma Awards



Ripple Science

Provides a research management software that is tailored to improve recruitment and retention in clinical trials by managing the patient and user experience during the planning and execution of a clinical trial

Company overview

- Ripple Science is a web-based software platform that reduces the time taken in clinical trials by improving patient recruitment, retention, and engagement through the use of technology. The company has so far conducted 3,200 studies in 10 countries
- Ripple Science offers solutions such as Ripple Recruit, Ripple Engage, and Ripple Registry, which are built to work well in clinical, transactional, and social science research environments
- It services academic institutions and life sciences companies such as Cornell University, Cognito Therapeutics, and John Hopkins University

Fact sheet

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	Year of incorporation	2016
	Key executives	 Peter Falzon, Chief Executive Officer and President Nestor Lopez-Duran, Founder Jacob Bonenberger, Co-Founder Daniel Ayala, Chief Information Security Officer
	Headquarters	Ann Arbor, Michigan
	Number of employees	11-50

Investor confidence – estimated total funding of US\$5 million

Domain focus	* *	*	*	*
Market buzz and history	* *	*	*	\Rightarrow
Disruption and core competencies	* *	*	*	\Rightarrow
Leadership and talent	* *	*	*	\Rightarrow
Overall	* *	*	*	$\stackrel{\wedge}{\Longrightarrow}$

Patient engagement offerings

Datacubed Health offers a DCT platform with solutions such as:

- Ripple Recruit is a recruitment management software that aims to improve all aspects of the preenrollment recruitment workflow, from campaign creation and pipeline management to screening and consenting
- Ripple Engage is a participant engagement and management software that aims to improve the way teams communicate and track enrolled participants and increase study retention rates
- Ripple Registry is a searchable patient registry that helps accelerate enrollment for future studies and helps build a custom research participant and patient registry

Partnerships

Partnered with multiple providers and hi-tech enterprises such as Microsoft, Lakeside Life Science, Purdue University College of Health and Human Sciences (HHS), and Curavit Clinical Research

Recognition and awards

Recognized as one of the 2021 awardees for the Michigan 50 Companies to Watch award, presented by Michigan Celebrates Small Business; Curavit Clinical Research and Ripple Science announced an expanded partnership with a three-year agreement



THREAD

Provides a decentralized research and eCOA platform designed for the life sciences industry which allows companies to design, operate, and scale clinical research studies

Company overview

- THREAD provides a decentralized research platform used by sponsors and CROs to design, operate, and scale patient-centric research with eight years of industry leadership
- THREAD provides a suite of research design consulting services and key platform features such as eConsent, complex eCOA, sensors, reminders, and telehealth virtual visits to support remote data capture, hybrid virtual, and fully decentralized studies

Fact sheet

Year of incorporation	2016		
Key executives	 John Reites, Chief Executive Officer Paul Taylor, Chief Product Officer Kim Boericke, Chief Operating Officer Stefan Cano, Chief Scientific Officer Keli Platco, Chief Strategy Officer and SVP of eCOA 		
Headquarters	Cary, North Carolina		
Number of employees	51-200		

Investor confidence - estimated total funding of US\$50 million publicly available as private equity backed

Domain focus	*	* *	*	\star
Market buzz and history	* >	* *	*	*
Disruption and core competencies	* 7	* *	*	*
Leadership and talent	* 7	* *	*	*
Overall	* 7	* *	*	*

Patient engagement offerings

THREAD offers a DCT platform with solutions that:

- Provide tools and strategies to identify, screen, recruit, and enroll participants in clinical trials efficiently in the clinic or at home
- Provide solutions for complex eCOA data collection (i.e., ePRO, and ClinRO)
- Provide solutions to collect data directly from Electronic Medical Records (EMRs)
- Provide digital solutions for obtaining and managing informed consent from participants remotely
- Support wearable and sensor devices that collect continuous health data from participants
- Provide platforms and tools to keep participants engaged and motivated throughout the trial, including educational resources and regular communication
- Provide data anonymization techniques to protect participant privacy
- Facilitate virtual consultations between participants and researchers

Partnerships

Partnered with multiple providers and hi-tech enterprises such as Amazon Web Services (AWS), Apple, Datavant, OpenAI, and SAS



YPrime

Provides a platform that aims to advance science and health by simplifying clinical trials through faster eCOA and IRT start times, and offers patient engagement solutions to improve retention through the delivery of personalized and predictive experiences

Company overview

- YPrime streamlines the clinical trial journey with a configurable platform designed for providing faster Interactive Response Technology (IRT) start times and electronic Clinical Outcome Assessment (eCOA) launch times. The company aims to advance healthcare by simplifying clinical trials from trial design to data lock
- YPrime's eClinical platform includes the following solutions eCOA, IRT, eConsent, and patient engagement, along with consulting services

Fact sheet Year of incorporation 2006 • Jim Corrigan, Chief Executive Officer Key executives Mohan Ganesan, Chief Financial Officer · Alison O'Neill, Chief Operating Officer · Lindsay Daniel, Chief Human Resources Officer • Steve Begley, Chief Compliance Officer Drew Bustos, Chief Marketing Officer Michael Hughes, Chief Product Officer • Mark Maietta, President and Chief Commercial Officer David Wallace, Chief Technology Officer Shawn Blackburn, President, YPrime Labs Headquarters Malvern, Pennsylvania Number of employees 201-500 Investor confidence Not publicly disclosed

Domain focus	* * * * *	
Market buzz and history	* * * * *	-
Disruption and core competencies	* * * * *	-
Leadership and talent	* * * * *	
Overall	* * * * *	

Patient engagement offerings

- YPrime eClinical platform helps to solve issues that sponsors face in clinical trials such as trial delays, protocol amendments, and data quality
- YPrime's patient-facing technology incorporates key engagement elements including user-friendly design, personalization, and behavioral science to drive engagement and protocol adherence
- YPrime eConsent platform streamlines informed consent in global clinical trials, ensuring compliance and ease for patients and sites
- YPrime's eCOA platform supports sponsors with faster implementation of protocol amendments and less time spent on User Acceptance Testing (UAT)
- Consulting services support data standardization, management, monitoring, and statistical support services
- · Beyond patient engagement, YPrime also provides Interactive Response Technology (IRT) for patient randomization and trial supply management. Key configurability features empower sponsors to modify text fields, change demographic questions, add/remove visits, revise dispensations, add new cohorts, and more

Appendix

Glossary

Research calendar



Glossary of key terms used in this report

Al	Artificial Intelligence	s the simulation of human intelligence and	decision-making capability by machines

ClinRO Clinician Reported Outcome is a measurement based on a report that comes from a trained health care professional after observation of

a patient's health condition

eCOA Electronic Clinical Outcome Assessment is a method used in clinical trials to collect patient-reported outcomes data electronically

ePRO Electronic Patient-Reported Outcome is a patient-reported clinical trial outcome collected by electronic methods

eConsent Electronic consent is a digital process that potential clinical trial participants use to give consent before and during a study

ITS Information Technology Services is the transfer of ownership of some or all information technology processes or functions to a service

provider. This could include core, administrative, delivery, or management-related processes or functions

ML Machine Learning is an application of AI that provides systems with the ability to automatically learn and improve from experience without

being explicitly programmed

ObsRO Observer Reported Outcome is a measurement based on a report of observable signs, events or behaviors related to a patient's health

condition by someone other than the patient or a health care professional

PRO Patient-Reported Outcome is a measurement based on a report that comes directly from the patient about the status of the patient's health

condition without interpretation of the patient's response by a clinician

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