Manifesto for Patient Mediated Research

Andaman7's plan to disrupt life sciences

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SUMMARY: Emerging trends in life sciences—such as the need for real world evidence, clinical research as a care option, decentralized clinical trials, the focus on equity and inclusion, patient-reported outcomes (PROs), rare diseases, and over-the-counter drugs—all underscore a critical need: **collecting significantly more data directly from patients**.

Andaman7 addresses this need with its advanced Personal Health Record (PHR), a mobile application that empowers patients to gather their comprehensive health data. Coupled with its integrated clinical research platform, Andaman7 enables patients to collect health data from diverse sources, such as hospital electronic health records, labs, medical devices, PROs, and mobile apps, and store it securely on their phones, **ensuring privacy, security, and regulatory compliance by avoiding cloud storage.**

With control over their data, patients are now able to participate in clinical research as driving partners as opposed to mere passive actors. We call this **Patient Mediated Research (PMR)**. Read on to discover the magic formula for next-generation clinical research:

A7 = PHR + PMR

We invite you to join us in shaping this future. Contact us today to explore partnership opportunities and learn how Andaman7 can revolutionize your clinical research efforts.

Introduction

The life sciences industry encompasses large pharmaceutical and medical device companies, as well as numerous smaller BioTech and MedTech firms. This includes supporting entities like Contract Research Organizations, patient recruitment agencies, clinical trial protocol designers, and regulatory consultants.

The primary goal of life science companies is to develop innovative treatments, such as pharmaceuticals, medical devices, and digital therapeutics, to prevent, manage, or cure diseases.

Developing new treatments is complex due to biological intricacies and strict regulatory requirements from bodies like the Food and Drug Administration (FDA) and European Medicines Agency (EMA). Traditional clinical trials are costly and time-consuming, with high failure rates. Securing reimbursement from payers, such as insurers, is another major challenge. Compiling a comprehensive regulatory dossier is crucial, requiring a large volume of data and documentation.

Emerging trends

In this context, **at least 11 significant trends** have emerged in the past few years:

1. Regulatory bodies and payers increasingly require **real-world evidence (RWE)** to demonstrate a treatment's effectiveness beyond controlled trials. This includes data from electronic health records, medical claims, and digital health technologies.
2. Authorities also request more **patient-reported outcomes (PRO)**, gathering input directly from patients.
3. The COVID-19 pandemic disrupted traditional trials, leading to the rise of **decentralized clinical trials (DCT)**. This approach enables greater inclusivity and equity by including participants far from trial sites.
4. Traditional trials often collect data during limited consultations. Enabling patients to provide **data at numerous intervals**, including from home, offers a more comprehensive view of health. This also supports **longitudinal studies** and the continuous population of **registries**.
5. Thanks to great advances over the past decades, more treatments have become available for **rare and ultra rare diseases**. However, these breakthroughs come with challenges, including how to ensure that (1) these treatments developed at high costs are affordable for often vulnerable and small patient populations and (2) rare patients can be recruited for clinical trials. Hence the importance of fostering a vibrant patient community.
6. **Clinical Research as a Care Option ("CRaaCO")** is the use of clinical trials for the care of patients with a serious disease and no effective treatment.
7. **Equity** is an ethical necessity as well as a drug efficacy necessity (due to individual / group genetic variations, environmental factors, etc.). **Disabilities** also hinder the contribution of some to research.

Enabling a **proxy approach** where caregivers close to the patient can help with the research is an important way to overcome this challenge.

8. **Collecting data on over-the-counter (OTC) drug use** in clinical trials is crucial for understanding potential drug interactions and their impact on trial outcomes, as many participants regularly use these medications. Accurate reporting helps ensure patient safety and provides a more complete picture of health during the trial. However, OTC drug usage is often difficult to capture reliably due to participant self-reporting and the view shared by patients that OTC drugs are not "medicine" in the same way as prescription drugs.
9. New study types are increasingly needed for regulators and payers. These include **health economics and outcomes research (HEOR), quality of life, comparator and market research, patient preferences, and all "type 4 studies"**. All these studies often require data from many sources, often requiring patient input.
10. **Patients are becoming care consumers.** Many patients are becoming more attentive to their health, and willing to participate in their treatment. This is especially true for chronic diseases. They have more choices and will shop around for what helps them best be in good health or be cured from a specific disease.
11. **Privacy regulations** are emerging everywhere. The first significant one is the General Data Protection Regulation (GDPR) in Europe, but there are similar initiatives now in California and 13 other US states, as well as in Brazil, China, and 100 other countries. Two key trends can be summarized as follows: (1) companies handling patient or citizen data must adhere to increasingly strict regulations to protect that data. (2) Individuals have growing rights to: have access to data about them, modify the data, get a copy, forbid a company to use their data , move the data to another company offering similar services, and be forgotten.

The need for patient mediated research

> These trends above show that, for the next generation of clinical studies, **a very large part of the data will need to be collected directly from patients**, in addition to collecting purely clinical data from doctors.

And if patients also have access to their health data residing in health systems, hospital / GP EHRs and in consumer medical devices… that is a lot of data that can be collected from patients.

We call this **patient mediated research (PMR)**.

Below, we list the key principles we believe PMR must adopt to fulfill its promise.

Key principles of PMR

- **Primary Focus on Health Management by and for the Patient:** Patients are primarily interested in managing their own health. Participating in a clinical study is a secondary benefit. This distinguishes our approach from others and highlights the value of a full Personal Health Record (PHR) as a cornerstone, rather than solely focusing on research participation.
- **Patient Empowerment:** Patients are central to the research process, actively managing and sharing their data. They are not just subjects but partners, having control over their health information and deciding what to contribute to studies. This active role ensures data accuracy and patient buy-in.
- **Privacy by Default:** Health data are stored securely on patients' devices, ensuring privacy and control. By avoiding cloud storage for health data, these data remain in the user's possession, building trust and adhering to stringent privacy regulations like GDPR. Patients grant explicit consent to share data.
- **Comprehensive Data Collection:** Gathering health data from all sources, including medical records, devices, and patient input. This holistic approach captures a complete health picture, encompassing clinical, lifestyle, and patient-reported data, leading to more robust and meaningful research outcomes.
- **Continuous Engagement:** Maintaining long-term relationships with patients for longitudinal studies and registry building. This sustained interaction allows for long-term data collection, crucial for understanding chronic conditions and the long-term effects of treatments, and fostering ongoing patient participation.
- **Inclusivity and Equity:** Ensuring diverse and equitable participation in research. By removing geographical barriers through mobile technology and providing accessible tools, PMR ensures that all demographics, including those with rare diseases or disabilities, can contribute to studies.

We expect that if we adopt these principles, the following benefits should emerge from PMR:

- **Continuous and Comprehensive Data Collection:** Access to real-world, continuous data provides a more accurate picture of treatment effectiveness. Real-time, patient-generated data, combined with clinical records, offers a more precise and comprehensive understanding of treatment outcomes compared to traditional, time-limited data collection.
- **Improved Patient Engagement:** Empowering patients increases participation and retention in studies. When patients feel in control of their data and understand their contributions, they are more likely to stay engaged in long-term studies, reducing dropout rates and improving data completeness.
- **Reduced Costs:** Efficient data collection and DCT can lower research expenses. By leveraging patient-owned devices and minimizing the need for physical sites, PMR streamlines the research process, cutting down on operational costs and resource allocation.
- **Faster Drug Development:** Streamlined processes and better data lead to quicker development of new treatments. Higher quality data and more efficient recruitment accelerate the research

timeline, enabling faster analysis and regulatory approvals, thus bringing new therapies to market sooner.

- **Greater Inclusivity:** Reaching diverse populations and those with rare diseases. PMR overcomes geographical and accessibility barriers, making it easier to recruit and engage patients from diverse backgrounds and those with rare conditions who might otherwise be excluded from traditional trials.

The Magic Formula

Andaman7 represents a significant shift in the landscape of digital health. We are pioneering a new way to conduct clinical research with a very different and much expanded approach. We believe it will seriously disrupt how clinical research is conducted.

Our approach is based on conducting PMR—while strongly adhering to the principles mentioned above—via the integrated use of the Andaman7 research platform. **In brief, the two key elements of the Andaman7 platform are described below:**

1. **PHR: The Andaman7 Personal Health Record empowers patients to consolidate medical data from various sources onto their smartphone, ensuring privacy and control**. Users can track health, manage records, and selectively share information while maintaining health data security through on-device storage.
2. **PMR: Andaman7's research platform leverages its core PHR functionality to create a powerful tool for DCT and RWE collection**. By giving patients control of their data, the platform facilitates direct participation in research, allowing them to contribute their consolidated health records and track relevant outcomes. Researchers can access anonymized and consented data directly from patients' PHRs, streamlining data collection and enhancing the richness of real-world datasets.

The PHR and the PMR (i.e., the research platform) are—quite uniquely—deeply integrated in the same software. Patients managing their health data on their smartphone who agree to participate in research using our proprietary platform receive additional data collection tools including, among others, a drug module, PRO questionnaires, screeners,[1] and consent forms.

When integrating these tools, we uncover our magic formula:

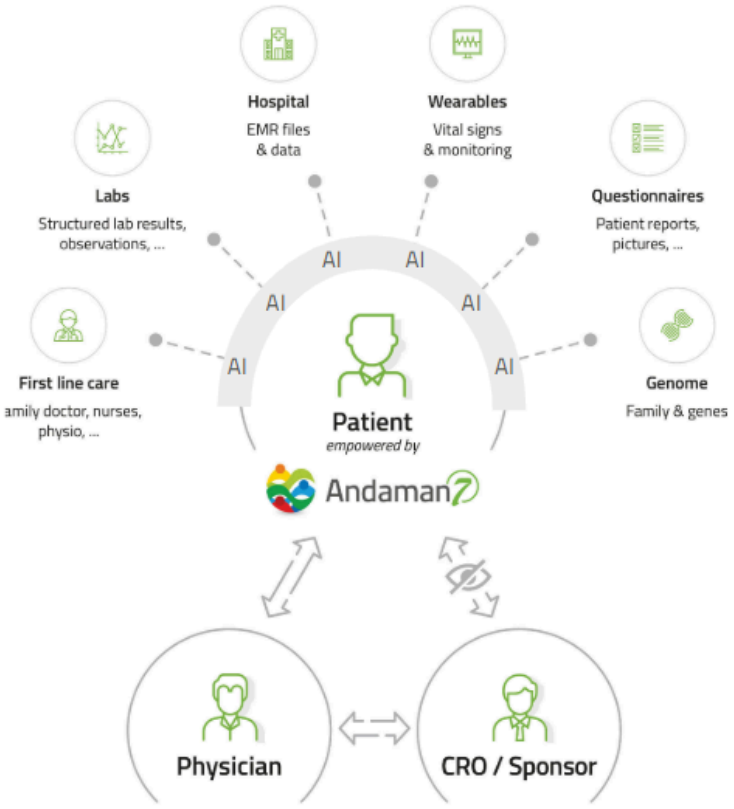
A7 = PHR + PMR

The magic formula for next generation clinical research

[1]Andaman7 includes a "screening" or "pre-screening" module that facilitates patient recruitment. Doctors or recruitment agencies can perform an initial selection of potential patients, and Andaman7 conducts the final screening. This also allows for the dynamic completion of sub-cohorts (e.g., a certain number of male/female, age ranges, etc.).

More details on the PHR and the platform are provided below.

The PHR - Andaman7 Personal Health Record



Unlike traditional systems that often silo patient data within institutional databases, Andaman7 empowers individuals to collect, manage, and share their health information. The platform's fundamental principle is patient control, enabling users to consolidate medical records and other health data from diverse sources, including hospitals, laboratories, pharmacies, and personal health devices (including, among others, glucometers, fitness trackers, and nutrition, or sleep apps). This consolidation creates a comprehensive PHR that the patient directly controls.

Our goal is clear: enable patients to collect all of their health data from all sources, in all countries and store all of that data on their smartphone in a very powerful but extremely easy mobile application called a PHR.

A critical aspect of Andaman7 is its unwavering commitment to data privacy and security. Recognizing the sensitivity of health information, the platform stores health data on the user's smartphone and adheres to stringent data protection regulations like GDPR and Health Insurance Portability and Accountability Act (HIPAA). In fact, Andaman7 does not have direct access to a user's health data and we simply provide a tool for patients to share their health data with researchers. This approach grants users unparalleled

control over their health data, fostering trust and encouraging active participation in their healthcare management.

The PHR is very easy to use for patients, currently in its 5th revision. But it is also a very advanced piece of software, supporting both structured and unstructured data, documents, codified data (Logical Observation Identifiers Names and Codes [LOINC],[2] Systematized Nomenclature of Medicine [SNOMED],[3] others) and basically any type of health information. See these documents for more information on the advanced innovations of the Andaman7 platform:

- Andaman7 Technical Innovations: https://bit.ly/a7TechInno
- Andaman7 advanced health data management: https://bit.ly/a7DataMan
- Andaman7 deep dive: https://andaman7.com/a7dd

The PMR - Andaman7's Patient Mediated Research Platform

Beyond personal record keeping using the PHR, Andaman7 facilitates seamless data sharing within a user's "Circle of Trust," which can include family members, caregivers, and healthcare providers. This capability enhances communication and collaboration, enabling informed decision-making and coordinated care. Moreover, Andaman7 extends its utility beyond individual patients, serving as a valuable tool for healthcare professionals and researchers.

Furthermore, the platform supports DCT and the collection of RWE, streamlining research processes and generating valuable insights into patient outcomes. Of note, the platform includes various modules such as eConsent, screening and cohort management, electronic questionnaires, powerful and flexible electronic PRO, electronic case report forms (eCRFs), an advanced drug management module[4] (managing both precise drug list and intake data, both for prescribed and OTC drugs), adverse events reporting, anonymization / pseudonymization and ways to collect data in a peer-to-peer approach, avoiding storage of health data in the cloud.

Andaman7's commitment to interoperability underscores its goal of seamless data exchange within the healthcare ecosystem. By adhering to established health standards like Fast Healthcare Interoperability

[2] LOINC is a universal code system for identifying health measurements, observations, and documents. Essentially, it's a standardized way to name and code laboratory and clinical test results.

[3] SNOMED is essentially a standardized, comprehensive clinical healthcare terminology, or in simpler terms, a universal dictionary for healthcare. It ensures that when a doctor in one hospital records a patient's diagnosis, a doctor in another hospital, or a researcher analyzing data, can understand that diagnosis in the same way.

[4] This "drug module" forms the basis of our treatment adherence system (which can be used both in care settings and during clinical studies).

Resources (FHIR),[5] SNOMED, and others,[6] the platform ensures compatibility with existing systems, fostering a more connected and efficient healthcare environment.

Integrating AI to Facilitate Care and Research

Adding to its already strong platform, Andaman7 is integrating AI.

For **patients**, Andaman7 uses AI to simplify complex documents with care and empathy. Documents can also be translated into other languages. We are also working on a capability to summarize the full health record of a patient, using a hybrid approach (AI + structured information following IPS[7] and EUPS[8] standards).

For **hospitals** and **sponsors of clinical research**, Andaman7 AI is making an important contribution to the challenges of data access (FHIR and non FHIR) and data usability (structured and unstructured information).

In the future, Andaman7 further plans to expand AI in ways that are beneficials to users and clinical research and that enhance privacy, security, and usability. For instance, Andaman7 plans to leverage "small language models" (SLM) to enable AI functionalities directly on users' smartphones. This approach involves utilizing smaller, more efficient AI models that run locally on the device, rather than relying on large language models (LLM) in the cloud, which is common among competitors. Critically, Andaman7 stores all health data exclusively on the smartphones themselves, a unique differentiator that cannot be easily replicated by comparable applications that typically store data in the cloud. This on-device data storage, combined with local AI processing (SLM), offers critical benefits, including enhanced privacy and security, as no sensitive health data needs to leave the user's device. Additionally, it provides computation benefits by reducing latency and dependency on internet connectivity, ensuring faster and more reliable AI-driven sub-applications. This localized approach also reduces server load and costs, making the

[5] FHIR is a standard designed to make it easier to exchange healthcare information electronically. It aims to break down the barriers that have traditionally prevented the seamless exchange of healthcare information, leading to improved care coordination and better patient outcomes.

[6] For instance: RxNorm https://en.wikipedia.org/wiki/RxNorm; Anatomical Therapeutic Chemical (ATC) Classification System https://en.wikipedia.org/wiki/Anatomical_Therapeutic_Chemical_Classification_System; International Classification of Diseases (ICD) https://en.wikipedia.org/wiki/ICD-10

[7] International Patient Summary - https://international-patient-summary.net

[8] EUropean Patient Summary - https://health.ec.europa.eu/system/files/2023-10/ehn_guidelines_patientsummary_en.pdf

solution more sustainable. Finally, it fully aligns with growing regulations on privacy worldwide - in other words, increasing regulations benefit Andaman7, while they hinder our competitors.

Mission-driven patient empowerment

Driven by the founder's personal experience as a cancer survivor and his young son's experience with cancer, Andaman7 has a strong mission of patient engagement and empowerment. **Patients receive our platform for free to manage their health data.** Patients have the option to simply manage their data or, with their informed consent, contribute to research by sharing electronic PRO and other health data with sponsors. Andaman7's revenue is generated through partnerships with life science industries that support efficient patient data collection.



Conclusion

Andaman7 is spearheading a revolutionary shift in clinical research through **PMR** - Patient Mediated Research.

By empowering patients with a comprehensive, secure **PHR** and a deeply integrated research platform, Andaman7 addresses the growing demand for RWE, DCTs, and patient-reported outcomes.

The core of our approach lies in patient empowerment, "security by design and privacy by default", and comprehensive data collection, leading to enhanced data quality, improved patient engagement, reduced costs, faster drug development, and greater inclusivity.

Driven by a strong mission of patient empowerment and a commitment to data democratization, Andaman7 is poised to disrupt traditional clinical research, fostering a collaborative and efficient ecosystem where patients are not just subjects but active partners in advancing healthcare and driving better outcomes for all.

Our magic formula, **A7 = PHR + PMR**, encapsulates this vision, marking a significant leap forward in the future of clinical research and personalized medicine.

We invite you to join us in shaping this future. Contact us today to explore partnership opportunities and learn how Andaman7 can revolutionize your clinical research efforts.