Aptar digital health

Leveraging Patient Community and Machine Learning for Early Identification of Patients in Clinical Studies

Accelerate and derisk your clinical study: two cases from Aptar Digital Health

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Introduction

Clinical trials are crucial for the development of new treatments, ensuring they are safe and effective before reaching patients. However, they face several significant challenges such as:

1. **Patient Recruitment and Retention**: Recruiting enough eligible participants is often one of the biggest hurdles. Many trials struggle to meet their recruitment targets, leading to delays. Retaining participants throughout the study is also challenging, as dropouts can affect the trial's validity.

2. **High Costs**: Conducting clinical trials is expensive, with costs associated with patient recruitment, data collection, monitoring, and more. Smaller biotech companies often find it particularly challenging to secure the necessary funding.

3. **Data Management:** Managing and analyzing the vast amounts of data generated during clinical trials is a significant challenge. Ensuring data accuracy, integrity, and security is crucial.

4. **Complex Trial Designs**: As therapies become more advanced, trial designs are becoming increasingly complex. Adaptive trials, which allow for modifications based on interim results, require careful planning and execution.

Addressing these challenges requires innovative solutions, collaboration among stakeholders, and a commitment to maintaining high scientific standards.

What does Aptar Digital Health offer?

Aptar Digital Health's study support services are tailored to meet the specific needs of each clinical trial. Our range of services includes:

1. **Initiation**: Development and review of study protocols, management of informed consent forms (ICFs), and preparation of study reporting.

2. **Recruitment**: Utilizing our 4+ million user database for patients' identification and real-time recruitment dashboards.

3. **Data Collection**: Digital subject onboarding, electronic patient-reported outcomes (ePRO), and data accuracy checks using our Study Platform data collection tool validated on hundreds of device/OS combinations.

4. **Support Site Visits**: Planning and execution of remote or face-to-face screening visits and providing smart reminders for medical appointments.

5. **Study Adherence**: Personalized task lists, neuroscience-based techniques to increase patient satisfaction, and incentivization modeling.

6. **Study End & Reporting**: Accelerated data lock, data analysis, and preparation of regulatory-formatted clinical study reports.

"Our collaboration has been exceptional; their end-to-end study support ensured a seamless process from planning to database lock. Their ability to communicate in the language of patients fosters inclusivity and understanding."

Head of Global Research & Clinical Development for a leader company in science of nutrition, medical and pharmaceutical solutions.

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Case Study I: Virtual Trial Service for a Phase II Study

A global company specializing in nutrition, active lifestyle, medical and pharmaceutical products sought to conduct a phase II clinical trial for a new migraine treatment. The trial faced challenges such as long run-in periods, complex stages, and dropout risks, necessitating innovative solutions.

Study Design Optimization

To address these challenges, we implemented a fully virtual setup with the following key features:

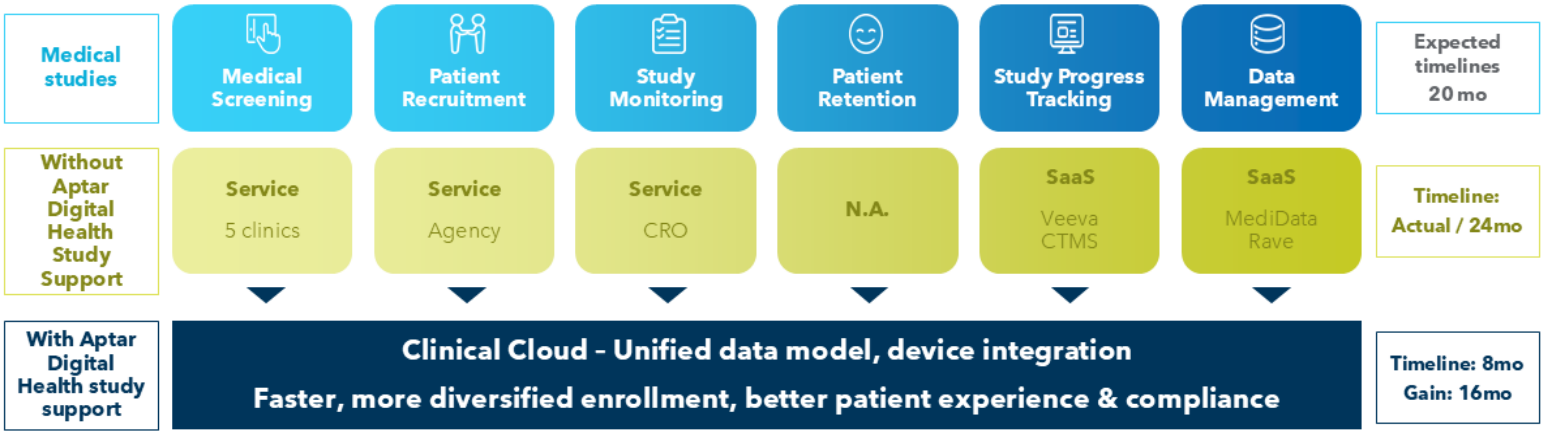
- Smart Recruitment: Leveraged targeted outreach to our platform users, achieving a low screen-fail rate. The study being virtual, patients did not have to be recruited in the vicinity of the site
- Clear Site Screening Appointment Booking: Simplified the scheduling of screening appointments.
- eConsent: Streamlined the consent process with electronic forms.
- Virtual Site Coach Team: Provided remote support to participants.
- ePRO: Collected patient-reported outcomes electronically.
- Compliance: Investigational Product intake monitored.
- Remote Patient Monitoring: Enabled continuous monitoring of participants.
- Dashboard: Sponsor had live access to a monitoring dashboard.
- Data management: Study databased managed and Lock accelerated thanks to live edit and logic checks.

Results and impact

The virtual trial service exceeded the client's expectations by:

- Fast Recruitment: High-quality subjects were recruited quickly.
- Enhanced Efficiency: Logistical challenges were minimized.
- Improved Engagement: Higher participant adherence was achieved; with a rate of 97% completion.
- Timely Insights: Real-time data capture enabled proactive intervention.

Aptar Digital Health capabilities allow to significantly reduce the duration of medical studies by integrating all needed services into a single platform, dedicated to this purpose



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Case Study II: End-to-End Service for a Real-World Evidence Study

A top 20 pharmaceutical company aimed to initiate a comprehensive virtual Real-World Evidence (RWE) study for an approved migraine treatment. Traditional methods posed significant difficulties, leading to prolonged recruitment periods and project durations.

Study Design Optimization

We optimized the study design with a fully virtual setup, incorporating:

- Smart Recruitment: Achieved a high screen-pass rate.
- eConsent: Streamlined consent process.
- Virtual Coach Team: Provided remote support though emailing.
- ePRO: Collected patient-reported outcomes electronically.
- Remote Patient Monitoring: Enabled continuous monitoring.
- Data management: Edit checks and logic checks were performed live to reduce the number of queries and accelerate the database lock.

Results and Impact

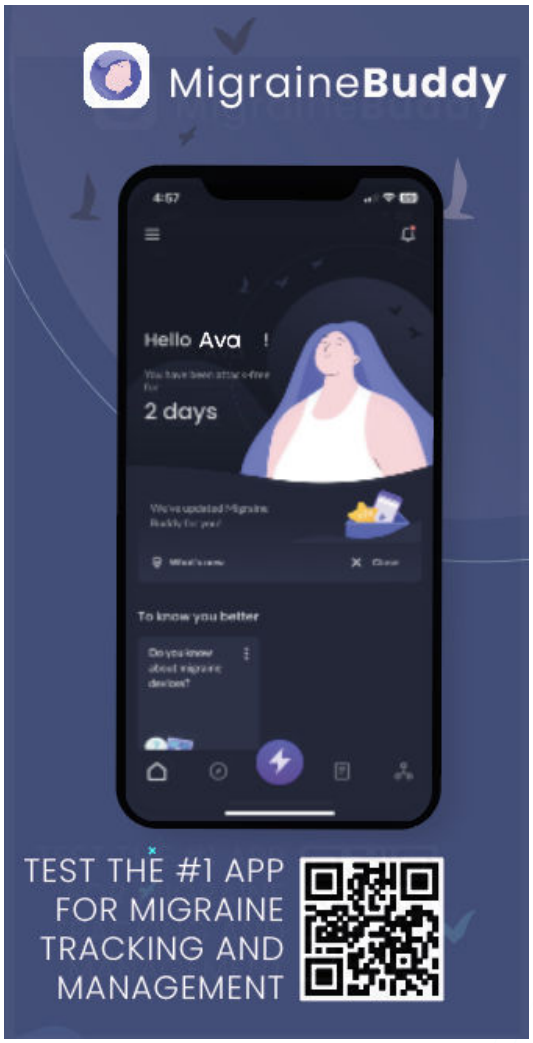
The end-to-end service delivered impressive results:

- Accelerated Subject Recruitment: **Completed 6 months ahead of schedule**.
- High Screen-Pass Rate: **Achieved a 74% screen-pass rate.**
- Exceptional Compliance: **Maintained a 64.8% compliance rate** with daily assessments.
- Outstanding Study Completion Rate: **Achieved a 92% completion rate**.

Why work with Aptar Digital Health?

Aptar Digital Health stands out in the industry due to our:

- Proven Record: Expertise in designing user-friendly platforms and handling pharma compliance challenges.
- Comprehensive Support: Experience across the entire product lifecycle, from phase 2 to medical affairs and HEOR studies.
- Data Quality: Commitment to providing the best quality data for studies.
- Innovative Solutions: Use of advanced digital tools to support study management.



Our mobile application **Migraine Buddy** is highly rated (125k+ reviews), with a 4.9-star rating on Android and a 4.8-star rating on iOS. By leveraging our Migraine Buddy solution with top pharmaceutical companies, we have demonstrated **our ability to deliver reliable, real-time data insights and maintain study data integrity.**

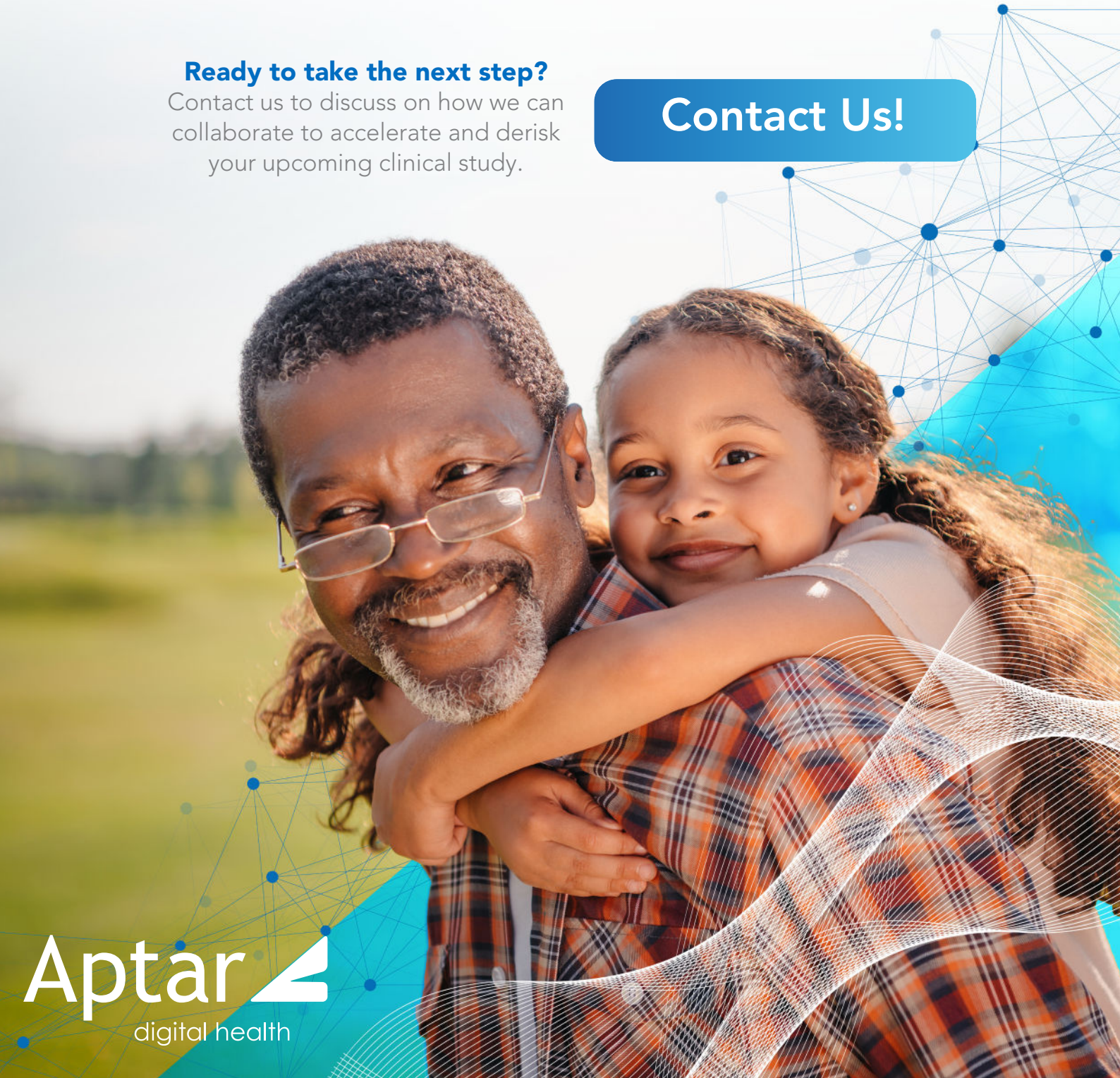
About Aptar Digital Health

Aptar Digital Health offers a comprehensive suite of study support services designed to address the critical pain points faced by pharmaceutical companies in clinical trial management. By leveraging our advanced digital health capabilities, we provide end-to-end support from trial initiation and recruitment to study completion and reporting. Our study platform ensures better data collection, patient management, advanced data analysis, and study predictability, making us a valuable partner for pharma companies.

Aptar Pharma's Digital Health division is part of AptarGroup, Inc., a global leader in drug and consumer product dosing, dispensing and protection technologies.

Ready to take the next step?
Contact us to discuss on how we can collaborate to accelerate and derisk your upcoming clinical study.

Contact Us!



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