

# Digital Device for Patient-Centric Clinical Trials

**Ideal for Decentralized or Hybrid Clinical Trials**



**EASY TO USE**

**PLUG & PLAY**

**CUSTOMIZABLE**

**SECURE**

**ECONOMICAL**

# Towards Patient-centric and Equitable Clinical Trials

Digital technologies offer opportunities and solutions that reduce cost, complexity, and burden.

Reliable connectivity, remote data capture, and robust compliance mechanisms are the backbone of decentralized clinical trials.

There is a need for more capable outreach for decentralized trials to populations of patients who often do not participate in clinical trials, e.g., rural communities, the economically disadvantaged, the elderly, and those living in remote locations.

Solutions for the economically disadvantaged without technological access (Broadband, Smartphones, Apps, and Computers) are crucial to a well-represented clinical trial.



## Benefits of Patient-Reported Outcomes (ePRO)

- Better understanding of patient needs
- Ensure better clinical outcomes
- Real-time feedback rather than at scheduled site visits
- Improves participant/protocol compliance
- Significantly reduces data collection time
- Higher quality data
- Accelerates Clinical Trials while Improving Patient Compliance

## Benefits of Medication Adherence

- Increase efficacy
- Helps identify compliance issues early on
- Decrease the risk of complications
- Nonadherence can increase variance, lower study power, and reduce the magnitude of treatment effects.
- Increase low patient compliance, which is a common problem in clinical trials
- Accelerates Clinical Trials while Improving Patient Compliance



# The Solution – How it Works?



**Patient stores the medication inside the container**



**RxKeeper® activity data transmitted via cellular device**



## **Clinical Trial Ecosystem**

In-house Sponsor  
Outsourced CRO  
Research Sites  
Real-time data for Clinical Trial staff

# The Solution – A Smart Container with Button Input



## RxKeeper® Features

- Cellular Connectivity - No Smartphone or App is required, and it works “out of the box.”
- ePRO - Track Quality of Life Questions
- ePRO and Adherence Data in Real-Time
- Plug & Play - No Paper forms, No APPs, No Smartphone or Computer Needed
- Easy To Learn and Use - even for the non-tech savvy!
- We can seamlessly push the raw data into your existing (CRO) platform!

**RxKeeper®** —the mobile container with a **battery-operated cellular notification system**—is designed for holding prescription bottles. It runs on 4 AAA batteries for 12-18 months. The patient is alerted at alarm time, even when the power is out.



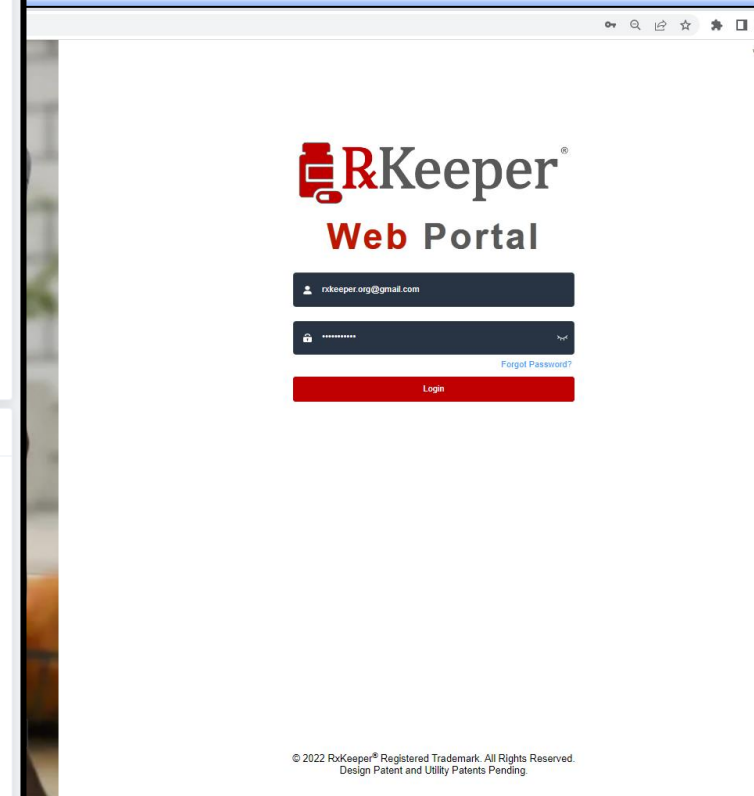
# For Clinical Trial Staff – Web Portal Dashboard Example



## Intended Users:

1. Inhouse/outourced Clinical Trial Staff
2. Providers

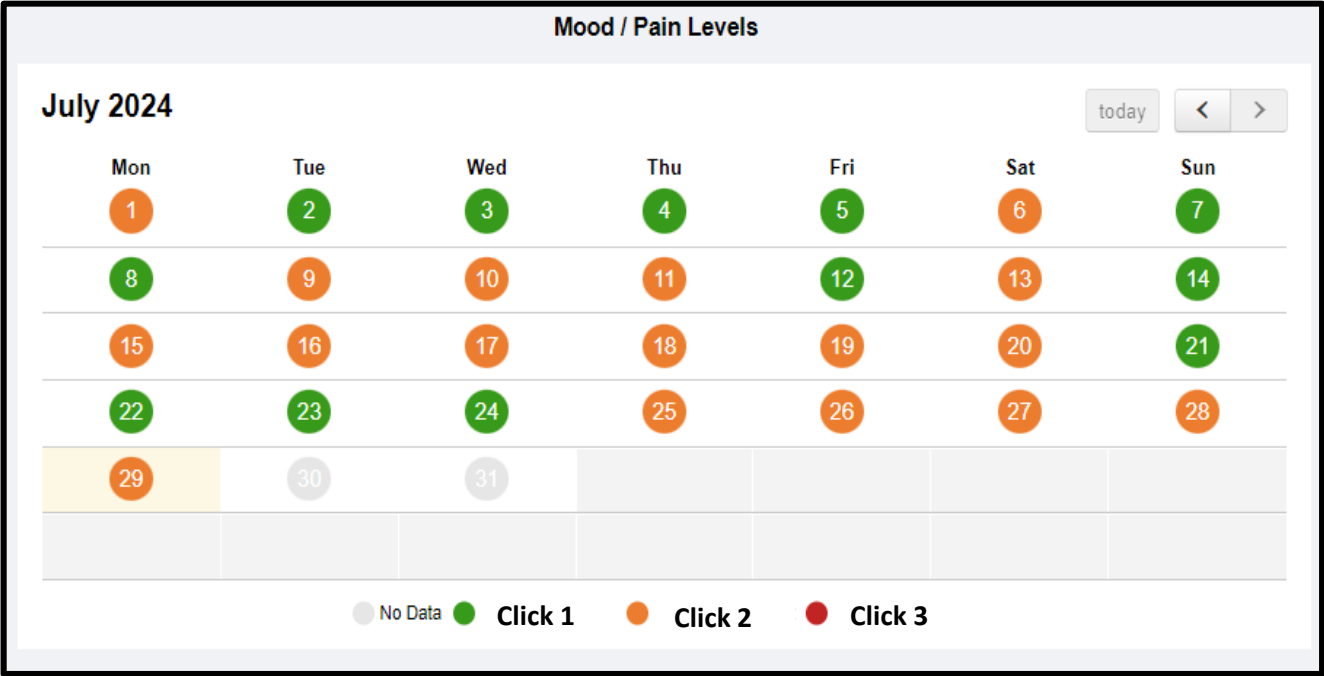
**Note: Raw data can be pushed to any server with proper authentication and security.**



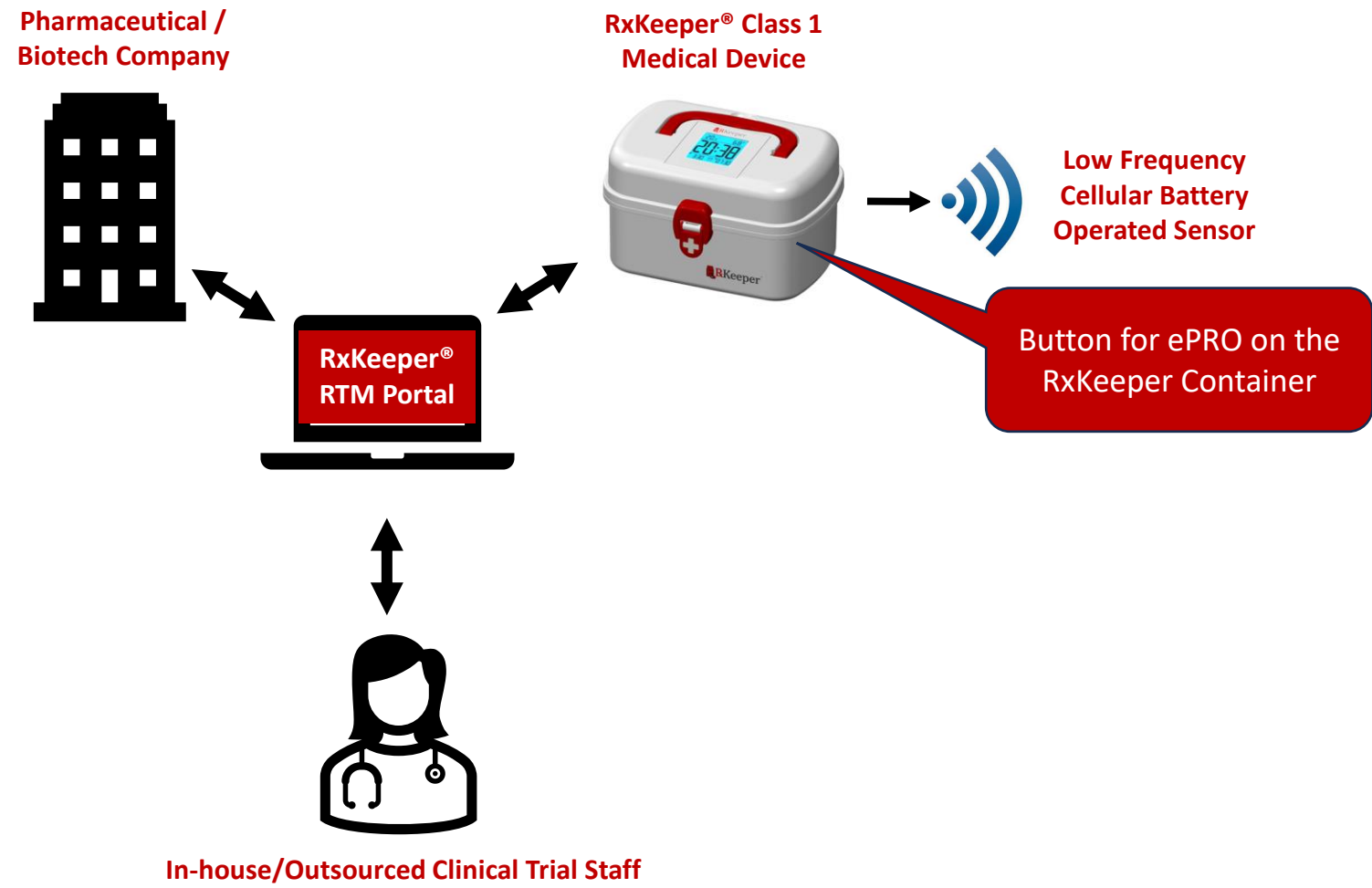
# For Clinical Trial Staff – Activity Dashboard Example

Quality of Life Questions	A little bit Click 1	Quite a bit Click 2	Very much Click 3
Do you have trouble doing strenuous activities?	✓		
Has your physical condition or medical treatment interfered with your family life?		✓	
How are your symptoms today?			✓

- The 3-Point Likert Scale is a powerful assessment tool for range interpretation
- Medication Compliance and Patient-reported Outcomes collected in real-time
- User-defined button activity: Click 1, Click 2, Click 3



# Entities – Turnkey Clinical Trial Solution





# Main Differentiators

1. Portable and battery-operated and cellular
2. Simplicity (Not over-engineered)
3. Usability (Minimal change in user behavior to encourage use)
4. Customizable (customizable notifications. Intuitive reminder cues for each person)
5. No Paper forms, No APPs, No Smartphone, or Computer Needed
6. Seamless capture of electronic patient-reported outcomes (ePRO) on the RxKeeper Container
7. Data is pushed to the cloud via a Country-wide Cellular LTE-M network (Low-Frequency IoT network)
8. Portal for the caretaker or family member to monitor user compliance with EHR integration for the providers or clinical trial team
9. Accelerates Clinical Trials while Improving Patient Compliance
10. Stronger Clinical Evidence with Electronic Patient Reported Outcomes for the non-tech savvy population





- Registered FDA Medical Device
- Patent Issued
- 250 Customers since January 2024
- 2500 MVP Version 1 Production Units available for launch
- **LIVE** in New Jersey – Spine & Pain Clinic
- **LIVE** in Atlanta – Orthopedics
- **LIVE** in Baltimore – Orthopedics
- **LIVE** in Florida – Orthopedics
- **RxKeeper** is also being used for the Medicare-reimbursable Remote Therapeutic Management program

[www.RxKeeper.com](http://www.RxKeeper.com)

**Successful Kickstarter  
Crowdfunding Campaign**



June  
2022

**FDA Registered Medical  
Device in 2024**



**Patent Issued in 2024**



UNITED STATES  
PATENT AND TRADEMARK OFFICE



## Dr. Nagesh Kadaba – Founder CEO

<https://www.linkedin.com/in/nageshkadaba/>

- Ph.D. in AI/Computer Science, MS. IP Law, BS EE
- The most prolific inventor with over 100 patents for UPS, including 11 patents in Healthcare Cold Chain Logistics used during COVID vaccine distribution.
- His IP protects innovative products that today generate over \$5 billion in revenue annually for UPS since 2000, and addresses inventions in areas such as e-commerce, computer-driven package delivery, automated package handling, and logistics, environmental sensors, and identity validation.
- Serial Intrapreneur as Director of Global Innovations at UPS for 26 years, transitioning to an entrepreneur after retirement

