



# CERTISCAN<sup>®</sup>

ADHERENCE MATTERS



## DIGITAL ADHERENCE





## Adherence Matters

In a typical trial, over 40% of patients will not take medication as prescribed. This non-adherence leads to suboptimal research, abandoned trials, unnecessary continuation due to uncertainty, and months of wasted time to market.

CertiScan<sup>®</sup> combines smart packaging, apps, and analytics to give timely insights, prompt behavioural interventions, and improved patient adherence - yielding **higher quality dose data and more effective research**. CertiScan's benefits also extend to GCP activities, facilitating adaptive trials, enabling decentralized and direct-to-patient scenarios, while also providing supply chain visibility and automating reconciliation tasks.

## It starts with high-quality data from smart packaging



### Med-ic<sup>®</sup> blister packs or eCAPs<sup>™</sup>:

Smart packaging automatically tracks every dose. Easy, contactless data retrieval using wireless NFC.



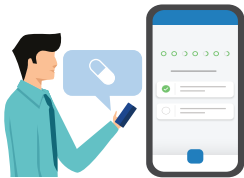
### Virtual Packaging:

Advanced eDiary features enabled with mobile apps.

## Software analyzes the data and creates value at every trial touchpoint

### For Patients - The CertiScan Mobile Apps

Collect and analyze real-time data to enable remote intervention strategies and trial decentralization. Choose between a simple collection mode, or a full mode with adherence-assisting features:



View daily medication schedule and receive reminders



Automatically track each dose intake on scan



Optional eDiary to manually record certain doses



Receive automated, targeted coaching messages



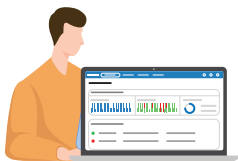
Track site appointment visits directly in-app



Motivation through gamification

### For Sites and Sponsors - The CertiScan Web Portal

Patient monitoring and targeted intervention strategies. Collect, analyze, and perform reconciliation on-demand.



Monitor each patient's adherence to a regimen



Receive alerts about aberrant use patterns



Adherence data insights and analytics



Uniform scripted coaching for site teams



Track study-wide adherence trends



Sync data with 3rd party systems using our API

### For Downstream Use Cases



#### Central Depot Post-Hoc Processing:

Trained staff collect data in standardized ways prior to destruction. Opportunities for automated dose level reconciliation are possible.



#### Generate reports and exports in many formats:

Use CertiScan web portal or REST APIs to access data, manually or automatically generate reports, etc.



## For Other Use Cases



### Package Management Tools:

Use CertiScan web portal to optimize trial logistics and reconciliation tasks. Or sync data with IRT/EDC/RTSM systems.



### Production Environments:

CertiScan Production and QA quality assures and provisions smart packaging. Opportunities to start trial supply chain traceability of smart packaging.

## Discover Previously Unknowable Trends and Insights



In traditional research, PK and PD data are not easily analyzed with adherence data. CertiScan automates analysis and highlights correlation allowing for interpolation between site visits. Additionally this facilitates the powerful ANCOVA analysis guidance from the FDA to improve the power of significance and the precision of the estimates of the treatment effect.



Traditional drug diaries and pill counts are error prone, tedious, and not conducive to remote or decentralized trials. CertiScan unit-dose tracking, reminders, and coaching are automated, mobile-first, precise, and do not burden patients or staff.



Up to 40% of patients deblist - they remove all pills into a bag or container for portability. This thwarts titration and harms drug stability. Deblistering and other aberrant use is detected in real-time using CertiScan smart packages, and automated mobile coaching helps patients correct their behavior.

## Our Commitment and Our Track Record

With CertiScan, the same (or greater) significance can be reached using smaller patient populations. **In short, reach last patient, last dose sooner.**

Every trial is unique and our specialists will work with all stakeholders to ensure a successful outcome. CertiScan has been used around the world for over 15 years, with 1.2M+ packages used in 100+ trials from more than 50 different pharma and research institutions. CertiScan has been used by sponsors to support FDA filings, and is the only adherence platform to support FDA priority review status for a blockbuster drug.

## Regulatory Compliance

CertiScan supports requirements for FDA 21 CFR Pt 11, EU Annex 11, HIPAA, and GDPR.





# Adherence Data Flow

It starts with high-quality data from smart packaging. We offer many types:

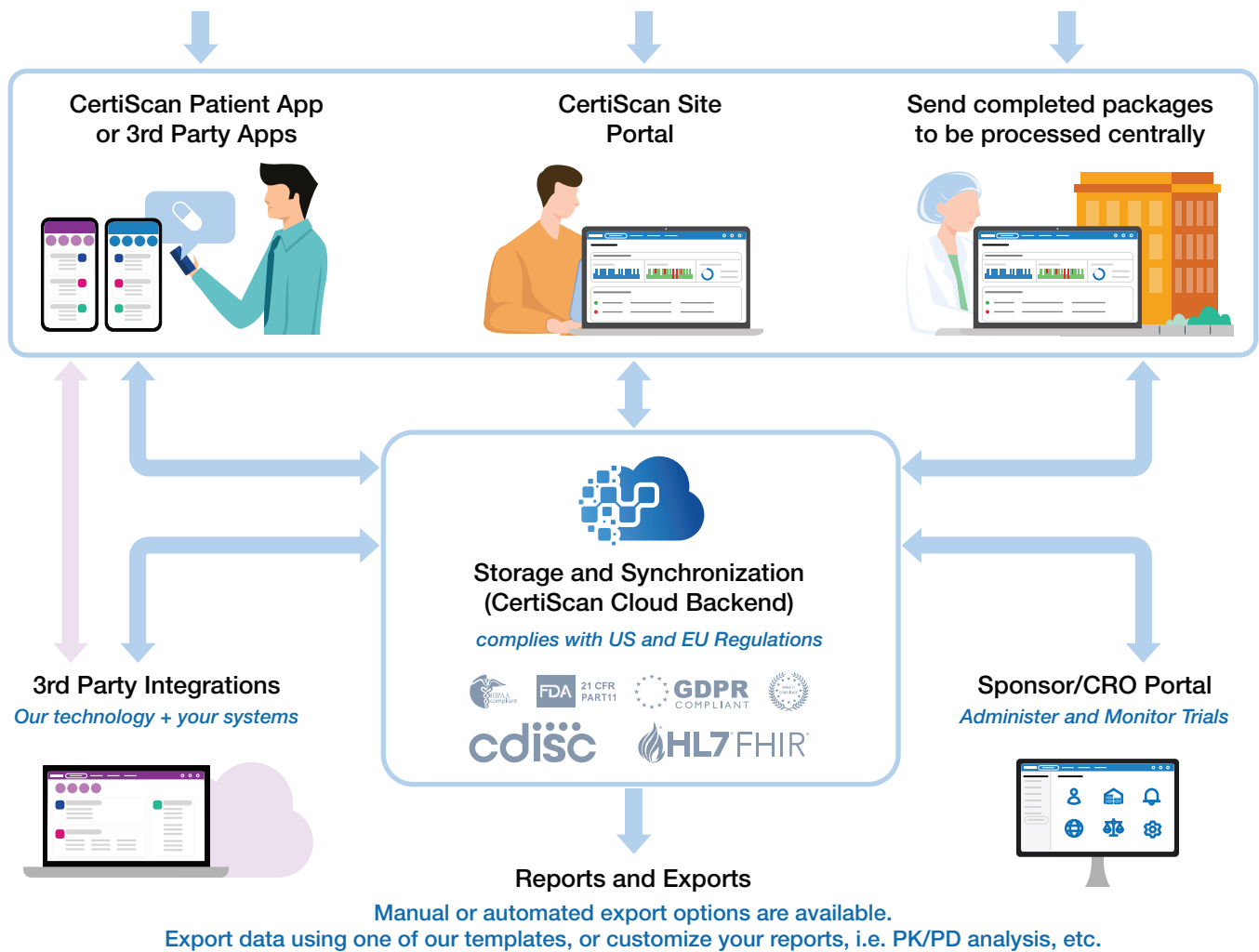


From there, many trial setups are possible, depending on your protocol:

*Data collection and analysis are real-time with patient scans. This enables remote intervention strategies and trial decentralization.*

*Data collection, analysis and drug reconciliation done periodically at site visits. Patient intervention strategies are also possible.*

*Data collection, analysis and drug reconciliation done post-hoc. Site and patient intervention strategies are also possible.*















# Smart Packaging

Smart packaging records patient dosing in real-time, and wirelessly transfers this data into the CertiScan platform.

Additional capabilities include:

-  Oral dose adherence monitoring with Med-ic for blistered medication and eCAP for bottled medication
-  Monitoring for syringes, vials and ampoules with Med-ic
-  Off-the-shelf or fully customized package designs
-  Supercharged Traceability: track IPs down to the unit-dose (i.e. per blister cavity on Med-ic)
-  Custom data may be written to the electronics for extended use cases (i.e. expiry date)
-  Packaging designs can be both CR (child resistant) and SF (senior friendly)
-  Integrates with CRO packaging workflows
-  Temperature excursion monitoring for temperature sensitive drug products with CoolBlue
-  Physical and virtual package adherence monitoring
-  NFC Forum certified wireless data retrieval





# CertiScan Adherence Solutions

Taken altogether, CertiScan consists of 4 different technologies:



**CertiScan Digital Adherence** - An end-to-end platform combining smart packaging, apps, and analytics to drive timely insights, prompt behavioral intervention and improved patient adherence.



**CertiScan Production and QA** - A GMP-validated system used during the drug fulfillment and carding process to ready CertiScan smart packaging for use in a clinical trial. *Refer to separate "CertiScan Production and QA" brochure.*



**CertiScan Integration** - A suite of mobile SDKs and REST APIs to provide 3rd party access to CertiScan platform data and services which can be leveraged to build 3rd party apps and connect seamlessly with IRT, RTSM and EDC systems. *Refer to separate "CertiScan Integration" brochure.*



**CertiScan Package Management** - A set of tools and integrations to provide logistics and reconciliation opportunities from the dosing data you already have. *Refer to separate "CertiScan Package Management" brochure.*

Each technology can be used independently or together to provide value from smart packaging dosing data. Using them together will maximize the value of the overall solution. To learn more, email: [adherence@certiscan.biz](mailto:adherence@certiscan.biz)

