



CERTISCAN[®]
ADHERENCE MATTERS



INTEGRATION





What is CertiScan®

CertiScan platform is an end to end system that combines smart packaging, apps, and analytics to give timely insights into patient medication adherence, prompt behavioural interventions, and improved overall adherence - yielding **high quality dosing data and more effective research**. CertiScan packaging and apps are meticulously designed to be patient-centric and easy to use: either standalone or seamlessly integrated with other trial software. CertiScan's benefits extend to GCP activities, enabling decentralized and direct-to-patient scenarios, while also providing supply chain visibility and automating reconciliation tasks.

CertiScan for Integration

CertiScan Integration is a suite of mobile SDKs and REST APIs allowing 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. CertiScan mobile SDKs and REST APIs use the latest technologies and security best practices to ensure a seamless and secure integration.

Regulatory Compliance

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



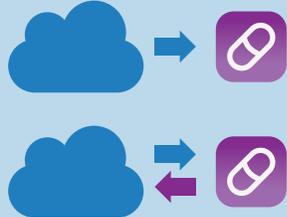
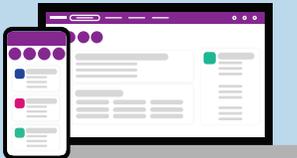


Integration Options

CertiScan allows 3rd party partners to read and write various types of data, including:

- **Patient Dosing Data:** Which dose was removed and when. Supports and automates patient coaching, accountability, and reconciliation activities.
- **Medication Adherence Data:** Metrics, analytics, and insights into how a patient or patient population is doing in the study.
- **Alerts and Guidance:** Actionable patient recommendations, automatically generated in response to specific non-adherence patterns.

Adherence packaging is manufactured and provisioned by IMC in the CertiScan platform. To accommodate different data I/O and user experience needs, integration options generally fall into 3 categories:

	Data I/O	User Experience
Tier 1	 <p>Pull data from CertiScan into a 3rd party system for further analysis and presentation. Many data formats are available (TXT, CSV, PDF, JSON, XML, etc). Transfer is typically in one direction.</p>	 <p>Patients and providers use the CertiScan mobile app and web app to collect, store, and visualize adherence data.</p>
Tier 2	 <p>Push and pull data from CertiScan to enable richer use cases. For example, pushing patient IDs and treatment details from an IRT into CertiScan at randomization time, avoiding double entry.</p>	 <p>Patients and providers use the CertiScan mobile app and web app to collect, store, and visualize adherence data. Redundant input by site staff is avoided through data I/O.</p>
Tier 3	 <p>Any I/O options from Tier 1 or 2.</p>	 <p>3rd party systems (powered by CertiScan SDKs, REST APIs and services) can collect, store, and visualize data directly within their own apps, mobile, desktop or web.</p>

Custom data formats, endpoints, and transfer protocols are possible for each tier.

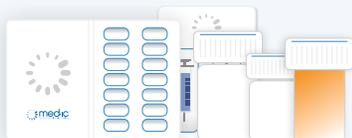


Data Flow

Data is generated from IMC's adherence packaging and flows into the CertiScan platform to be retrieved by the 3rd party.

Tier 1

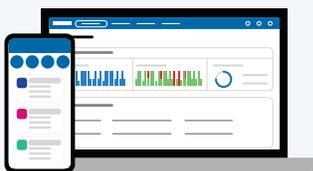
Adherence packaging records dosing



Retrieve dose info via NFC scan



CertiScan apps retrieve, analyze and visualize adherence data



1st party apps use CertiScan cloud for secure central storage, trial administration, analytics, and reporting

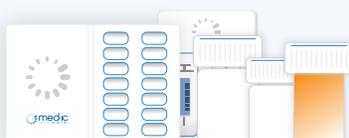


Pull data from CertiScan into a 3rd party system



Tier 2

Adherence packaging records dosing



Retrieve dose info via NFC scan



CertiScan apps retrieve, analyze and visualize adherence data



1st party apps use CertiScan cloud for secure central storage, trial administration, analytics, and reporting



Push and pull data from CertiScan into a 3rd party system



Tier 3

Adherence packaging records dosing



Retrieve dose info via NFC scan



3rd party apps (powered by CertiScan SDKs, REST APIs and services) retrieve, analyze and visualize adherence data



3rd party apps synchronize data using their own cloud backends, or can optionally also use CertiScan cloud for secure central storage, trial administration, analytics, and reporting



APIs and SDKs

CertiScan currently offers REST APIs and mobile SDKs, with options for custom APIs.



REST APIs: Access patient data in the CertiScan cloud infrastructure. Upload and retrieve patient adherence data, generate reports, perform reconciliation activities, and enhance your supply chain with unit-dose monitoring. All endpoints support OAuth2 for the latest security and SSO best practices.

Mobile SDKs: Your own apps can retrieve smart package data easily and wirelessly over NFC. SDKs are available on both iOS and Android. NFC is a frictionless, widely-supported technology, which allows patients to BYOD: bring their own device. SDKs can also enable on-device adherence data processing and analytics.

Outputs and Reports

CertiScan can generate output in numerous formats, including:



JSON



Text, tabular-based reports - CSV and similar



PDF Patient Reports



Embedded dynamic web-based displays

Output and report format may be customized per study requirements.

Developer Resources

To ensure 3rd parties can rapidly and effectively work with CertiScan, IMC provides:



API/SDK documentation



Hardware development kits



Sample code



Technical support





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. *Refer to separate “CertiScan Digital Adherence” brochure.*



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.



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

