CertiScan®

ADHERENCE MATTERS

ADHERENCE SOLUTIONS

www.certiscan.biz

IMC | INFORMATION MEDIARY CORP.

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.

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.

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**

Regulatory Compliance

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

CertiScan® 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® 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

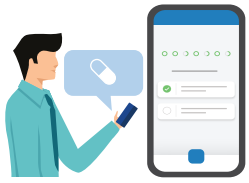
Med-ic® blister packs or eCAPs™:
Smart packaging automatically tracks every dose. Easy, contactless data retrieval using wireless NFC.

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

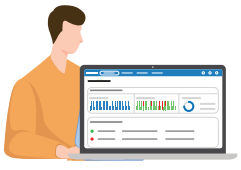
Collect and analyze real-time data to enable remote intervention strategies and trial decentralization. Choose between a simple collection mode, or a full mode with adherence-assisting features:



- 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

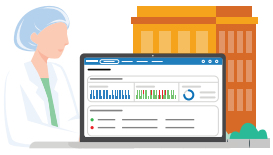
For Sites and Sponsors - The CertiScan Web Portal

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

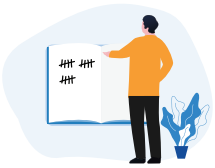


Central Depot Post-Hoc Processing:
Trained staff collect data in standardized ways prior to destruction. Opportunities for automated dose level reconciliation are possible.

Generate reports and exports in many formats: Use CertiScan web portal or REST APIs to access data, manually or automatically generate reports, etc.

Discover Previously Unknowable Trends and Insights

In traditional research, PK and PD data are not easily analyzed with adherence data. CertiScan automates this 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 deblister - 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.

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
- 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)
- Temperature excursion monitoring for temperature sensitive drug products with CoolBlue
- Off-the-shelf or fully customized package designs
- NFC Forum certified wireless data retrieval
- Physical and virtual package adherence monitoring
- Integrates with CRO workflows

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:

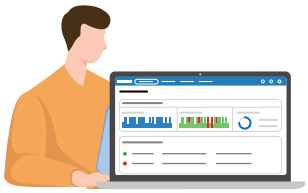
Data collection and analysis are real-time with patient scans. This enables remote intervention strategies and trial decentralization.

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

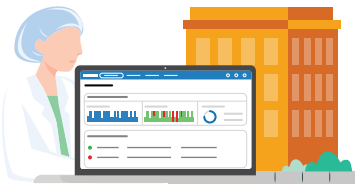
Data collection, analysis and drug reconciliation done post-hoc. Site and patient intervention strategies are also possible.

CertiScan Patient App or 3rd Party Apps

CertiScan Site Portal



Send completed packages to be processed centrally



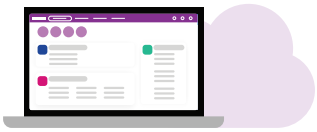
Storage and Synchronization (CertiScan Cloud Backend)

complies with US and EU Regulations

HIPAA compliant · FDA 21 CFR PART11 · GDPR COMPLIANT · cdisc · HL7 FHIR

3rd Party Integrations

Our technology + your systems



Sponsor/CRO Portal

Administer and Monitor Trials

Reports and Exports

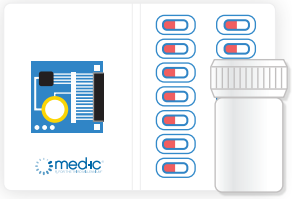
Manual or automated export options are available.
Export data using one of our templates, or customize your reports, i.e. PK/PD analysis, etc.

CertiScan® Production and QA

CertiScan for Smart Packaging Production and QA

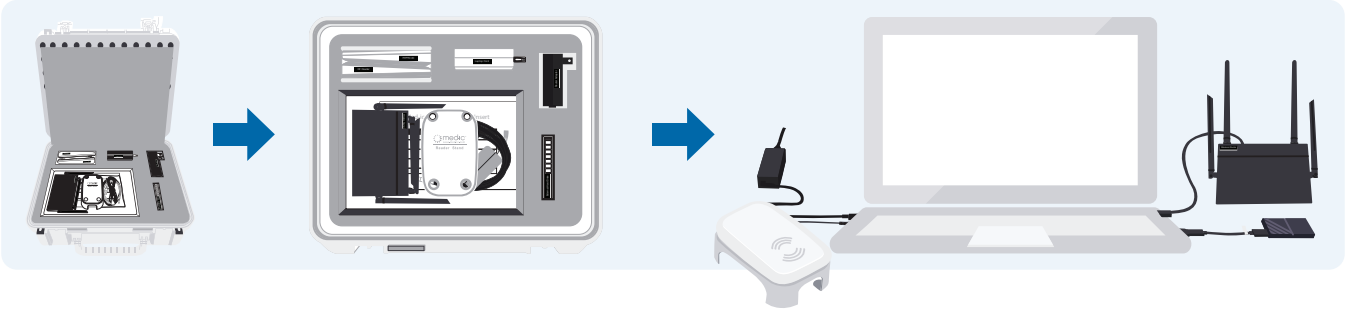
CertiScan Production and QA is a GMP-validated system used during the drug fulfillment and carding process to ready CertiScan smart packaging for use in a clinical trial. CertiScan Production and QA works seamlessly and comfortably within GMP packaging production environments using existing materials, processes and equipment. Production staff can be fully trained on CertiScan smart packaging in as little as a few hours. CertiScan specialists are available at all times for training and GMP production.

CertiScan Production and QA fully provisions and verifies correct CertiScan smart packaging operation, after which packaging can be distributed to patients to start the collecting of **high quality dosing data**. CertiScan Production and QA works with Med-ic (a blister package with embedded electronics) and eCAP (an electronic, standard threaded pill bottle cap) smart packaging.



Production and QA Kit

CertiScan Production and QA is provided as a kit comprised of multiple workstations and contains everything your staff needs to quality assure and provision CertiScan smart packaging.



Features

- Works with most blister, bottle or injectable packaging formats
- Easy reconciliation and work management
- Supports supervisor and operator role functions
- Works with existing processes and equipment
- Supports waterfall and pipelined work flows
- Meets GMP regulations, FDA 21 part 11, EU Annex 11
- Full suite of reporting
- CertiScan Production and QA data can be used downstream to unlock additional value
- Deployable on in-house IT infrastructure using customer-defined database

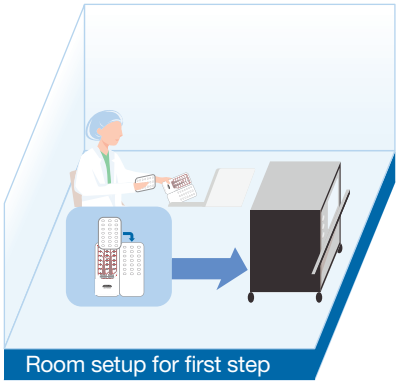
Workflow Details

CertiScan Production and QA organizes smart packaging work into jobs or lots with separate roles for line supervisors and operators. Work is then further divided and organized into 3 steps.

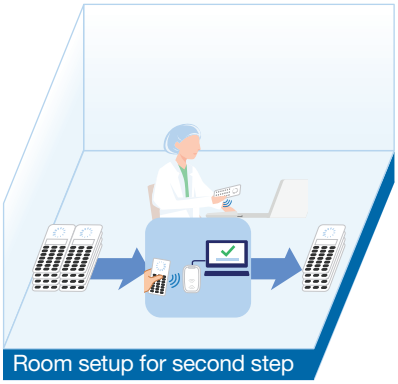
One or more workstations can be deployed at the same time in the same production room. Workstations easily network with each other to support any type of production workflow. There are two general workflow options (but mixed workflows are also supported).

1

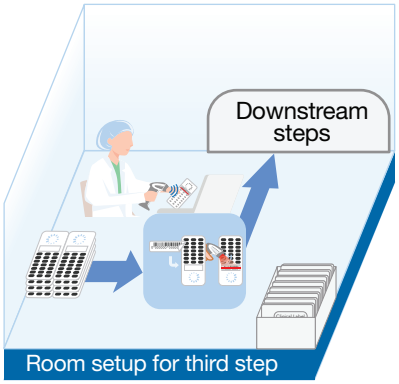
Waterfall: One (or more) workstations work concurrently on one production step at a time in the production room. CertiScan Production and QA is switched between steps when the entire lot is ready to move to the next step. **This workflow prioritizes simplicity.**



Pre drug fill/heat seal IQC: Packaging is confirmed to be fully operational before committing drug product to filling and heat sealing.



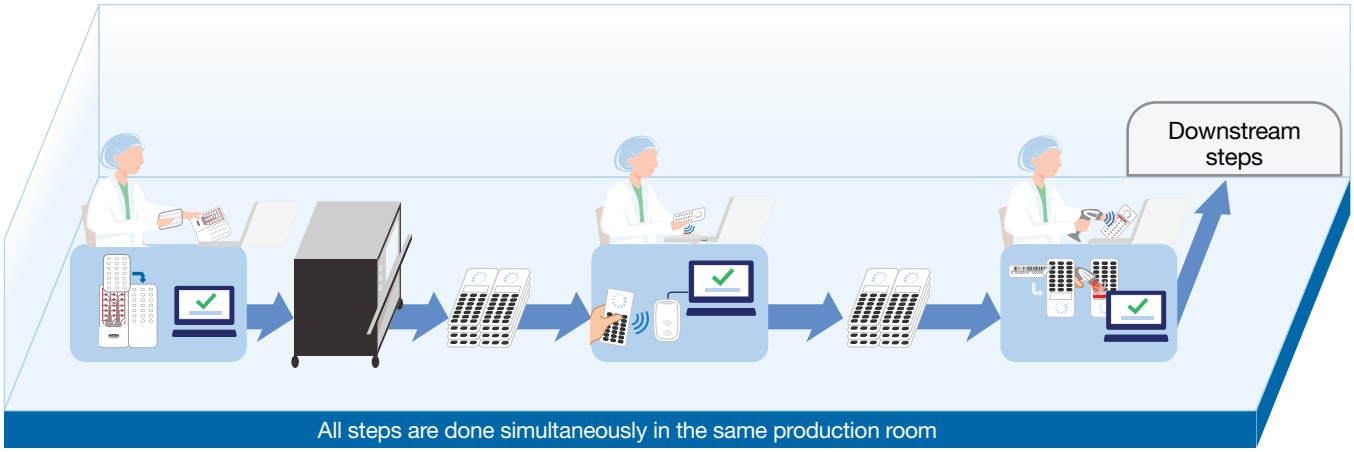
Post heat seal/drug fill QA: Packaging is verified to be fully operational after heat seal. Packaging will be fully provisioned and assigned all necessary study traceability information.



Verification: This activity is a 200% check on all packaging data before kitting and boxing occurs. After this, full reconciliation reporting can be done.

2

Pipelined: Multiple workstations work concurrently on multiple steps at the same time, in the same production room. **This workflow prioritizes throughput.**



CertiScan® Integration

CertiScan for Integration

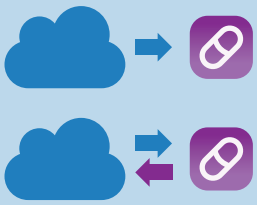
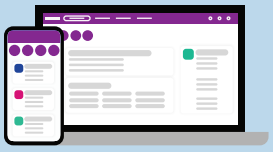
CertiScan Integration is a suite of mobile SDKs and REST APIs allowing 3rd party access to CertiScan platform data and services which can be leveraged to build 3rd party apps and connect seamlessly with IRT, RTSM and EDC systems. CertiScan mobile SDKs and REST APIs use the latest technologies and security best practices to ensure a seamless and secure integration.

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	 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.	 Patients and providers use the CertiScan mobile app and web app to collect, store, and visualize dherence data.
Tier 2	 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.	 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.
Tier 3	 Any I/O options from Tier 1 or 2.	 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.

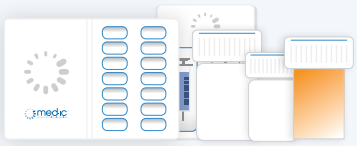
Custom data formats, endpoints, and transfer protocols are possible for each tier.

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

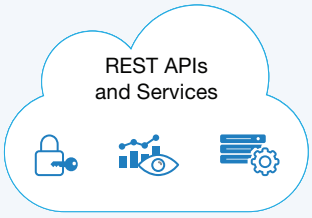
Adherence packaging records dosing



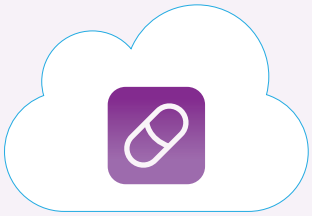
Retrieve dose info via NFC scan

CertiScan apps retrieve, analyze and visualize adherence data

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

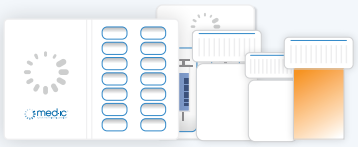


Pull data from CertiScan into a 3rd party system



Tier 2

Adherence packaging records dosing



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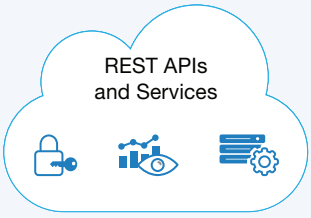
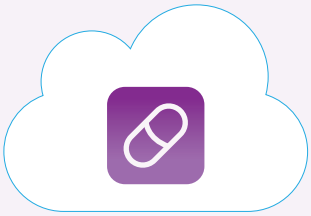
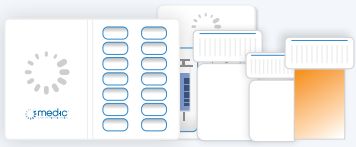


Push and pull data from CertiScan into a 3rd party system



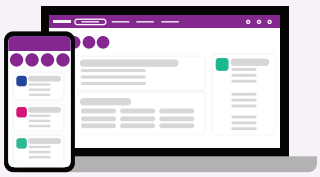
Tier 3

Adherence packaging records dosing

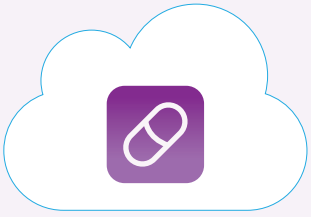


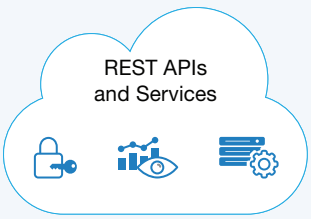
Retrieve dose info via NFC scan

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



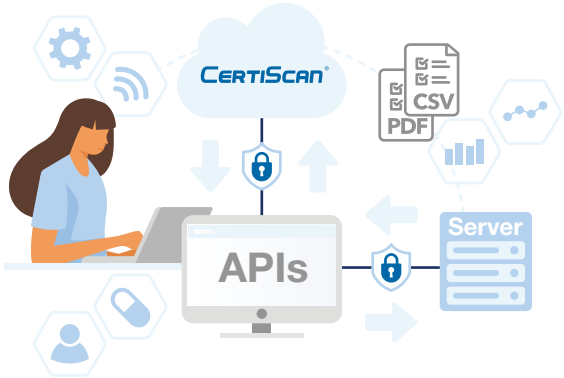
3rd party apps synchronize data using their own cloud backends, or can optionally also use CertiScan cloud for secure central storage, trial administration, analytics, and reporting





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®
Package Management

CertiScan for Package Management

CertiScan Package Management builds on the dosing data from CertiScan smart packaging that you already have and CertiScan technologies already in place to provide further opportunities to optimize trial logistics and reconciliation activities.

Complete GCP reconciliation activities faster, easier and passively

- Automatic drug reconciliation in real-time
- Drug and package destruction tracking
- Reporting by package, kit, and dose
- Full FDA submission, reconciliation reporting

Enhance your supply chain with passive monitoring

- Package damage or misuse alerts ensure patients receive valid, safe packaging
- Security: Anti-counterfeit technology ensure authenticity of package contents
- Temperature tracking and excursion alerts help staff discover and deal with spoilage early on
- Fine-grained logistics and tracking: per-dose with Med-ic, per-opening with eCAP
- Inventory insights that assist sites with resupply