INFORMATION MEDIARY CORP.
Medication Adherence Experts

IMC Brief On Adherence Intelligence

Abstract

With 90% of clinical trials failing[1] to meet FDA approval, researchers, regulators, sponsors and other stakeholders have worked tirelessly to identify causes of such high failure rates; many reasons are cited, including failure to meet statistical endpoints, insufficient patient enrollment, safety issues and failure to meet FDA protocols. Yet four contributing factors associated with existing trial design have material impacts as well: heterogeneity of trial populations, low patient compliance (50%)[2] with protocols, analog monitoring tools (75% of trials use diaries)[3] and cumbersome data management practices that make informed recommendations more difficult.

Serious examination of trial design throws a spotlight on a mission critical flaw that greatly undermines the efficacy of a clinical trial: research managers do not have real-time, objective knowledge of patient behavior. Latency of data access results in increased costs throughout all trial phases and compromises patient safety as well as data management that often produces false conclusions about the efficacy of a new drug.

Information Mediary Corporation has been a global leader in support of clinical trials for more than 20 years with its Smart Packaging technology that tracks real-time patient adherence. The devices are scalable and interoperable with other platforms; the tools have also supported many global trials. Its data capture system replaces subjective patient-reported outcomes with 100% objective data that can be used in many ways to improve the efficiency and efficacy of a trial, help trial managers engage patients with interventions that support adherence and trace each dose throughout the chain of custody, lowering patient recruitment costs, streamlining waste and simplifying documentation.

IMC's CertiScan platform supports trial sites with real-time dashboards that follow every patient's behavior throughout the trial and collaborates with other platforms to support data feeds when required.

IMC transforms the management of a clinical trial by addressing the latency of a research team's knowledge to mitigate cost and efficacy issues with current methods.

Revolutionizing Clinical Trials With Adherence Intelligence

Since 2001, Information Mediary Corporation (IMC) has been the global leader in providing real-time remote patient monitoring services that track patient adherence behavior in clinical trials. The company uses its patented ECM (electronic compliance monitor) devices that employ smart packaging technologies for pill caps and blister packs to track every dose and enable efficient, accurate medication management, which is a significant breakthrough in the pharmaceutical industry. Unlike other monitoring services that generate less reliable, subjective, patient-reported data, IMC uses time-stamped features with its ECM devices to feed objective patient data to its analytics and documentation platform, CertiScan.The platform then provides powerful visualizations for clinical research teams that drive actionable insights, prompt behavioral intervention and improve patient health outcomes that reduce trial costs, streamline supply chain management, lower waste and expedite document reconciliation for submission to the FDA.

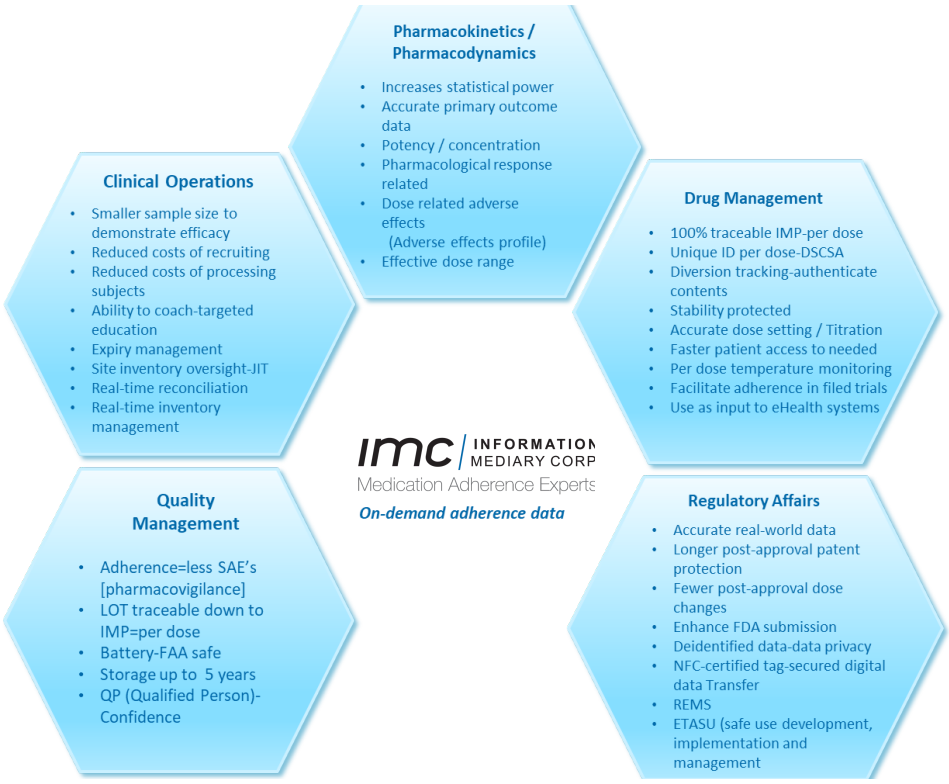
IMC has supported hundreds of clinical trials with Global Top 20 pharma sponsors, university research groups, CROs and other partners to serve more than 1.2 million participants. Two recent Use Cases:

1.IMC supported the Seattle Children's Hospital in a study of how adolescents use opiates following their surgeries. Insights: there was large variability of need for meds and electronic tracking was far more accurate in evaluating adherence than patient diaries; 33% of pill supply was saved as adolescents didn't follow protocol for dosage frequency.

2.Gilead studied adherence to its antiviral therapy for Hepatitis C. Insights: electronic blister packs clarified actual adherence levels and provided the research team with more precise estimate of effect of time on nonadherence. Analytics suggested comparable medication efficacy at lower dosage levels.

Case Study: AbbVie retained IMC for its monitoring solutions in13 trials to evaluate its medication for the management of endometriosis-associated pain and other symptoms. The FDA approved the use of Elagolix (Orilissa™) in July 2018.

Benefits to All Stakeholders



Problem Statement:

Data Variability In Clinical Trials Undermines Their Efficacy

With 90% of clinical trials failing[1] to meet FDA approval, a myriad of reasons have been cited: issues with patient safety, funding challenges, failures to meet FDA standards for manufacturing protocols, insufficient panel size and failure to meet statistical endpoints[1], to name a few.

Yet, four key considerations must be taken into account when devising a protocol that will increase the probability of a trial's success:

1. Trial panels are inherently heterogenous.
2. Patients don't adhere to trial protocols.
3. We have antiquated monitoring tools.
4. We need Adherence Intelligence data to measure efficacy at the individual patient level.

These four factors contribute to data variability, which reduces the power of conclusions one may draw from a trial and even produce contradictory findings from similar trial results. Clinical research teams compensate by adding more patients, yet patient shortfalls are the #1 contributor to failed trials in the U.S.

1) Trial Panels Are Inherently Heterogeneous

BioMedCentral produced a paper in 2017 on statistical inferences from clinical trials that addressed heterogeneity in trial populations:[4]

"One of the primary design parameters in a clinical trial is sample size. Large sample size is supposed to ensure statistical power of the study when the knowledge of causes and mechanisms of the underlying biomedical processes and effects of the compared interventions is insufficient for outcome prediction…in spite of all the effort, the queried population is still heterogeneous. There is one case, however, where the heterogeneity and independence problems are non-existent, namely when a sample consists of just one subject: N=1.

"Theoretically, greater distributional homogeneity of responses in a clinical trial could be achieved through stratification with respect to observable clinical variables. However, due to the large number of strata, the requisite sample size in many individual strata will be unachievable, thus making the trial underpowered, and the presence of substantial hidden variation will still leave individual strata heterogeneous.[4]"

In summary, "even for large-scale randomized controlled clinical trials commonly viewed as the gold standard of biomedical research, the "heterogeneity curse" will likely make the results of statistical inference…potentially lead to false and irreproducible conclusions.[4]"

2) Patient Don't Adhere To Trial Protocols

One of the prerequisites for a sponsor to achieve success in a clinical study is timely access to patient adherence data. This access guides the sponsor's understanding of patient behavior and the efficacy and safety associated with dosage amounts as well as timing and frequency of drug use. Patients are required to follow strict protocols designed to test specific hypotheses surrounding the effectiveness of a newly introduced medication.

If they 1) adhere fully to the protocol and 2) the sponsor knows its monitoring tools provide objective, verifiable data on patient behavior, life would be easier for the clinical operations team. But patients don't adhere, with trials often experiencing 50% drop-off rates against protocol guidance, and current monitoring methods often rely on patient reported, subjective data. Ultimately, this data is linked to metrics on the drug's efficacy and side effects, producing imprecise and often incorrect conclusions about the drug.

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Figure 1 illustrates the typical slope of adherence over time with 40% of patients becoming nonadherent to an investigational medical product (IMP) after 150 days. Applied Clinical Trials[5] conducted the study, where 16,907 participants were sourced from 95 clinical studies ranging from 30 to 1,400 days.

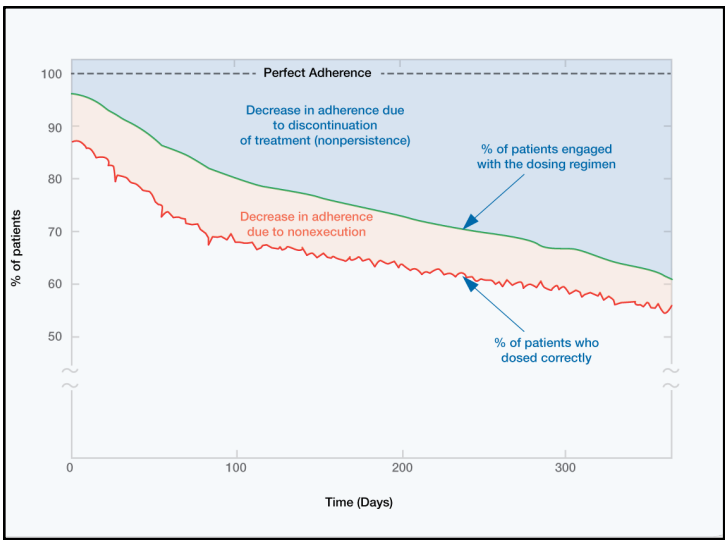

Figure 1

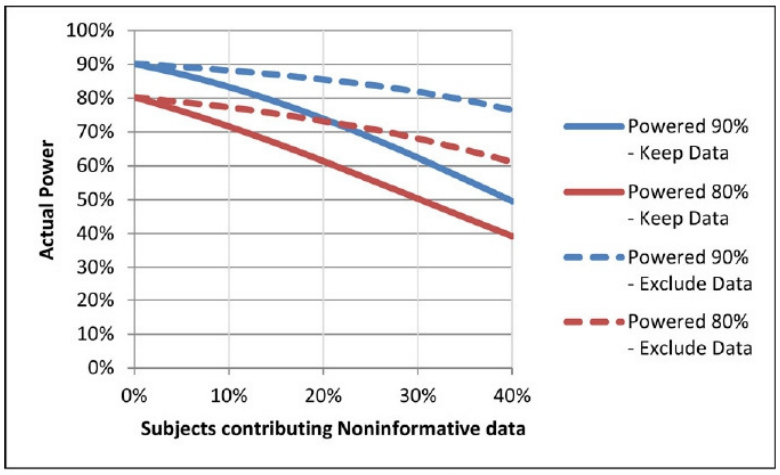

Figure 2 shows that if noninformative data are included, then a study intended to be powered at 90% would have an actual power between 50% and 87% depending on the percentage of subjects (10%–40%) contributing noninformative data.[2]

Figure 2

Nonadherence during the conduct of a clinical trial creates data that are false or misleading, violate the processes of hypothesis testing, and subvert efforts to determine the true safety and efficacy of investigational compounds ….needlessly exposing patients to adverse events, preventing potentially important medications from reaching patients, and costing hundreds of millions of dollars annually in research and development spending.[2]

It has been estimated that it takes only 30% of participants to be less than fully adherent to require doubling the number of participants necessary to produce an equally significant study…..Such is the impact of this statistic that simply eliminating noninformative subject data and replacing them with informative subject data is more efficient than increasing sample size while retaining noninformative data.[2]

Suboptimal adherence prevents trials from determining exact dose response curves and optimal dosing for real-world conditions. Failure to determine drug efficacy and safety in Phase 2 is the leading reason for trial failures in phase.[2]

Problem Statement:
Data Variability In Clinical Trials Undermines Their Efficacy

3) We Have Antiquated Monitoring Tools

Trial managers are often burdened with manual, patient-reported data capture tools derived from paper or electronic diaries, which are inefficient, costly and prone to error. Approximately 75% of trials still rely on paper[6] collection as their primary tool and Figure 3 reveals the many challenges incurred from manual methods. It may take weeks or even months for a research team to retrieve the information, organize it and assemble documentation it can provide to the FDA.

The absence of a real-time view into patient adherence combined with antiquated collection methods greatly reduces our understanding of patient behavior and weakens the accuracy of our trial assessments, creating outcome and financial risk to the patient, the sponsor and those supporting the trial. Depending on a variety of factors, this risk could be modest or fully open-ended and may contribute to the number of failed trials.

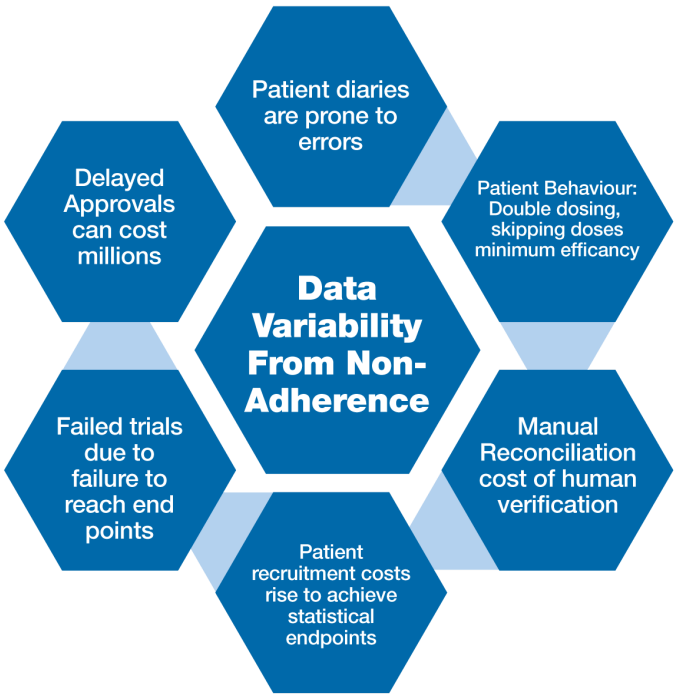

Figure 3

Five key areas of trial management are adversely affected by reduced adherence visibility:

1. Patient recruitment and retention costs grow: to compensate for not having access to non-adherent patients, trial managers expand participant pools to reach their statistical endpoints. Over enrollment is a tactic used to ensure enough patients participate. But this an expensive and time intensive approach.

2. Supply traceability costs grow: sponsors must dedicate extra manual resources to uphold transparency of each dose throughout the chain of custody for each dose.

3. Waste: costs seen in both excessive dosages distributed and in personnel time which occurs when a sponsor lacks the knowledge of where each dose is located.

4. Reporting and documentation costs grow: Principal Investigators convert manual diary data into documents for the FDA, which is cumbersome, expensive and time consuming.

5. Enhanced data risk: when the FDA approves provisional use following Phase III, if Real World Evidence does not corroborate with the trial findings—especially around dosage levels and frequency of recommended use—a sponsor may have to pull its drug off the market, pending a full reassessment of the trial data.

Good News: The Emergence of New Monitoring Tools

A new class of Smart Packaging technologies has the potential to radically change the face of clinical trials and fundamentally improve success rates. Easily administered and used by patients, they track real time adherence and support active monitoring activities and inventory management. The Global Health journal published a report in June 2021, "A Review On Emerging Smart Technological Innovations In Healthcare Sector For Increasing Patient's Medication Adherence," which examined several innovations in tracking patient behavior:

Digital active monitoring technology helps physicians (and clinical trial managers) cross-verify that patients have taken their dosage regimen at right time or not…and builds an interactive platform for communication between patients and physicians. There are various merits of using digital patient compliance tools such as reduced manual monitoring and documentation work that will ultimately enhance the efficiency of a clinical trial, with enhanced flexibility in deciding complex therapeutic treatments and trial workflows, decreased delinquency rate due to poor or inadequate compliance, enhanced data quality, shortened duration of clinical trials and accelerated approval process for new drugs and medicines.[3] Smart Packaging enables remote patient monitoring that can identify potential dosing problems early in a trial. Granular and specific data generates a greater understanding than diaries and other paper methods can provide. Studies leveraging Smart Packaging for medicine adherence and clinical trial site intervention have shown 20% increase in adherence levels.[7]

Furthermore, by gathering detailed dosing information and patterns of patient behavior, clinical researchers may be able to stratify subjects according to their levels of adherence and better understand the dose-response rate and "forgiveness" of an investigational product. New types of analyses could further correlate actual dosing patterns to determine when the medication might be most effective in a real-world setting.

We need Adherence Intelligence to Measure Efficacy At The Individual Patient Level

We define Adherence Intelligence (AI) as the outcome of matching composite patient profile data with composite adherence behavior throughout the trial. Objective data capture from real-time monitoring ensures that many discreet attributes of a patient's profile can be paired with their individual response to the medication—both in timing against meds taken, as directed by the trial protocol, and the level of efficacy for that individual. Adherence intelligence enables insights about the true safety and efficacy of an investigational product...and may help trial managers reduce costs as a result of improved power, lower enrollment, and shorter trial duration.[8]

Analysis can be measured on an N=1 basis and conducted across an entire patient panel to improve the probability of an accurate assessment of a medication's likelihood to reach its statistical outcomes. "But without this, statistical inference from clinical trials would essentially be a ritual that lacks scientific underpinnings and may have disastrous effects on public health.[8]"

In summary, AI and its promising analytics are not possible with paper or electronic diaries, or other current methods that only capture subjective patient-reported data. This is a fundamental weakness of current trial protocols.[8]

Description of IMC Services

IMC offerings are grouped into three services to provide a complete solution for Adherence Intelligence in clinical trials:

1. Remote Patient Monitoring
2. CertiScan Data Management
3. CertiScan Mobile App

1) Remote Patient Monitoring

Remote patient monitoring (RPM) presents trial managers with real-time visibility into knowing participants are actively taking the drug as directed by the protocol. RPM alerts the sponsor on when to trigger a resupply, and eliminates guesswork if patients are actively dosing or not. For patients not actively participating, contact is made to determine the cause and what steps need to be taken. Rather than automatically resupplying the non-adherent patient and potentially wasting drug supply, the clinical monitor is alerted to determine what the issue(s) are and contacts the patient.

Interaction pf patients with clinicians establishes the level of confidence patients have in the medication. The vitality of confidence and trust for the clinician is critical to patient adherence, as the time spent in addressing patient concerns can build a better relationship between patient and clinician, enhancing compliance with the protocol.[2]

IMC offers several wireless devices (Figure 4) that capture adherence and present actionable data in real-time to guide a trial. These devices track patient behavior associated with oral and subcutaneous medications. They are especially helpful in supporting hard-to-reach populations, including patients in rural settings and those who sponsors and CROs find otherwise expensive and physically difficult to support.

• Patented ECM (electronic compliance monitor) devices employ smart packaging technologies for pill caps and blister packs to track every dose, enable efficient, accurate medication management and deliver data accuracy to improve trial integrity, patient outcomes and ultimately accelerate new drugs into the market.

• ECM technology can also help identify adverse reactions to medication, ensuring the patient's safe use of any prescribed medication.

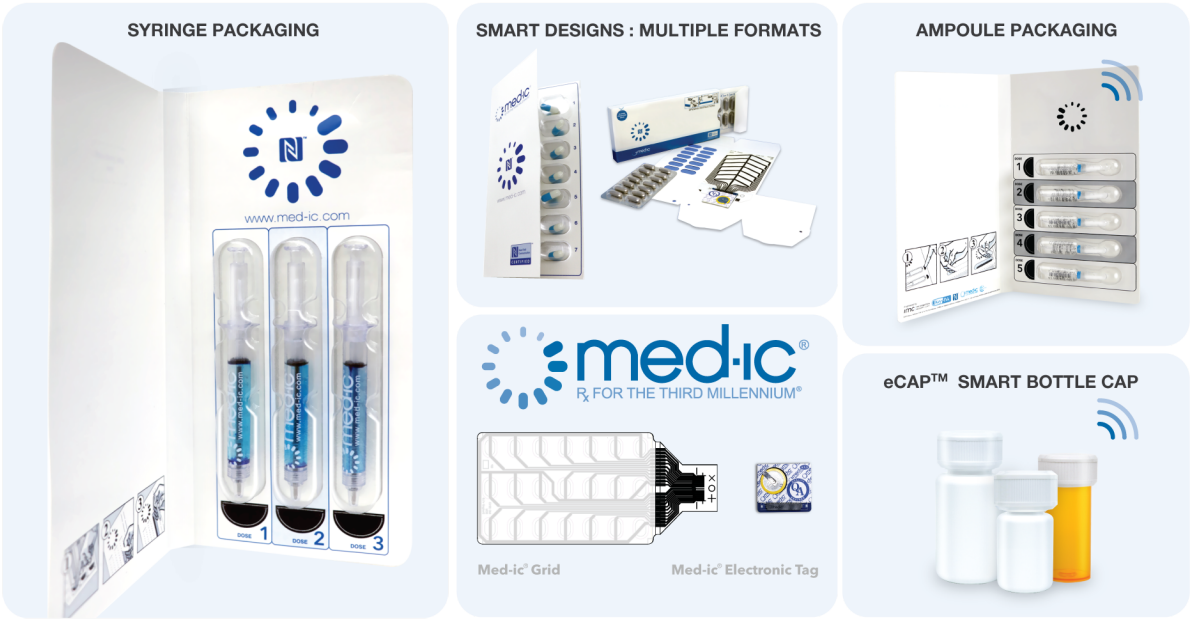

Figure 4

Description of IMC Services

Med-ic Smart Medication Blister Package

The only smart blister to have ever been used to collect adherence data for an FDA-approved blockbuster drug trial and offers a valuable solution to the issue of medication adherence in clinical trials. The package provides real-time monitoring of medication dispensing, enabling clinical trial sponsors to ensure that patients comply with their medication regimen. This technology is a breakthrough in clinical research and enables pharmaceutical firms to obtain accurate adherence data, supporting the development of safe and effective drugs.

eCAP Smart Medication Bottle

Rated the most accurate tracker in the market by Cincinnati Children's Medical Hospital, the eCAP helps patients take the right medication at the right time, significantly reducing the risk of adverse events. Patients can receive alerts on their smartphones when they miss a scheduled dose.

Med-ic and eCAP

Can be used independently or together to provide a comprehensive adherence and data management system during clinical trials. The Smart Medication Blister Package and Smart Medication Bottle work together to capture real-time data on patient medication usage, providing clinical researchers with accurate and comprehensive adherence data to support drug development.

The Med-ic and eCap are now NFC-forum certified and can be engineered with add-on features for logistics and RTSM to:

• Detect temperature excursions.

• Map to drug expiration date that can be remotely changed even after shipping.

• Report remaining dose counts to inform inventory, stocking and supply processes.

• Support collaborations with third parties to integrate CertiScan with their tools:

• Enable smart package scanning in third party apps with the CertiScan SDK.

• Exchange data with IMC's cloud using FHIR-based APIs.

These devices enable improved patient engagement which fosters higher adherence rates and generates accurate patient data. The devices are designed to be scalable and have supported trials on a global basis. They work with other adherence devices as well.

The Foundation of Accurate Monitoring

Intelligent packaging technology cuts waste, reduces risk and helps to optimize trial designs. Each unit dose has a unique ID that is tracked in real-time from point of packaging through to patient dosing.

These unique electronic identifiers eliminate all manual data entry processes and provide clinical monitors with real-time drug accountability, real-time drug reconciliation and insight as to how patients are or are not taking medicine.

Intelligent packaging's greatest strength is its ability to generate high-fidelity objective data, providing a solid, accurate foundation for supply chain forecasting systems. Together with remote monitoring, this potent combination aligns the precision of package data with the analytical prowess of AI engines, leading to smarter, faster, and more accurate decision-making, thereby refining the effectiveness of clinical trials, reducing waste and overall guarding patient retention.

2) Data Management and Analytics Platform: CertiScan

CertiScan is a rich web portal that receives data collected from remote monitoring devices and organizes it into a dashboard that compares real-time adherence per patient, between patients, between patient populations, or even between sites or different studies. The platform provides powerful visualizations that drive actionable insights, prompt behavioral intervention and improve patient health outcomes that reduce trial costs, streamline supply chain management, lower waste and expedite documentation for submission to the FDA.

CERTISCAN®

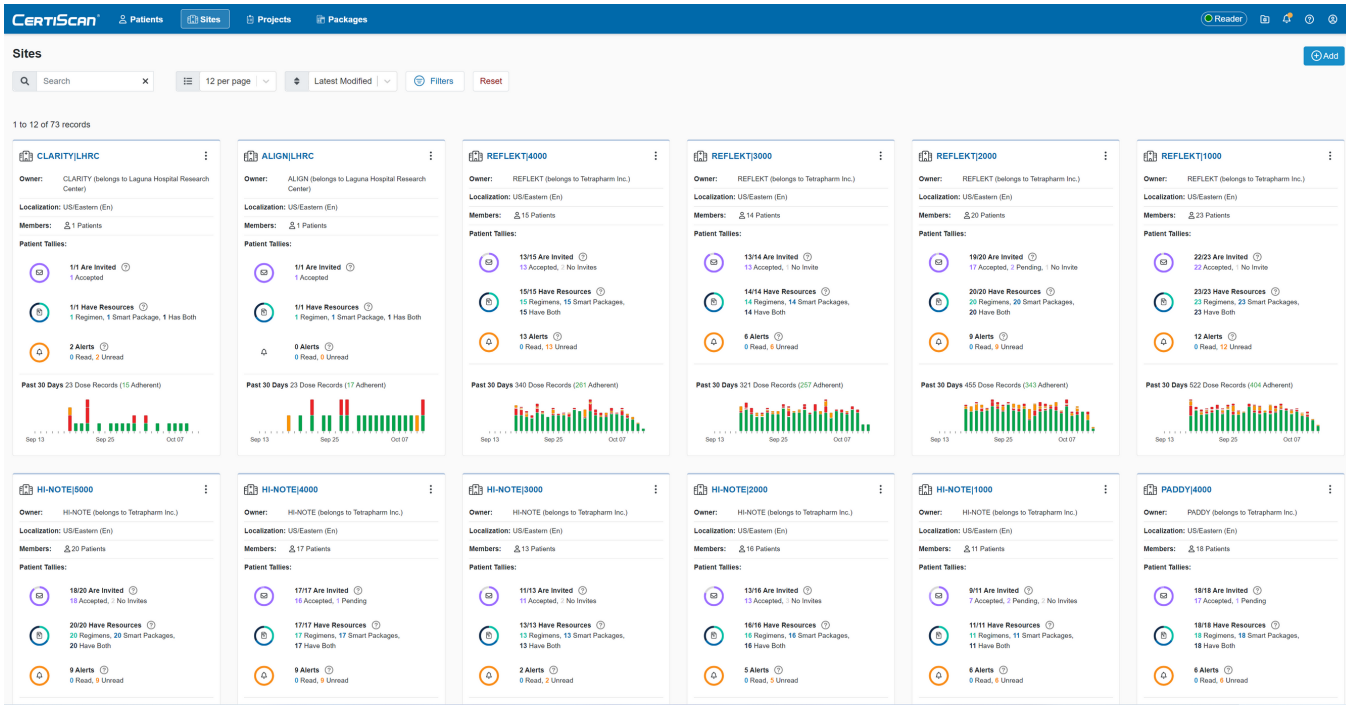

Figure 5: A sample screen provides a dashboard of patient compliance across all sites in a trial.

2) CertiScan Mobile App

CertiScan Mobile App supports patient self-tracking, medication reminders and targeted automated coaching akin to a Fitbit for medication adherence that helps prevent and mitigate drops in adherence. The mobile app can also detect aberrant behavior and send informative, targeted coaching messages to the patient's phone as soon as an aberrant event is detected. Trial site staff are also notified.

Benefits and ROI of IMC Solutions

By capturing real time patient adherence data during a trial, IMC delivers a set of important benefits that unfold throughout the trial. Its objective data alerts a research team when monitoring its participants to take corrective measures that keep patients engaged and compliant with the trial protocol. IMC's tools also help research teams better understand the behaviors of their participants, so they can be more effective when managing behavioral interventions. Below are a set of benefits that accrue throughout the trial, saving research teams potentially millions of dollars, improving the accuracy of their data and establishing a basis for better outcomes.

Benefit	Benefit Explanation
Improved Adherence	• Improve patient engagement with reminders educational messaging on an as-needed basis. • Sponsor and CRO more easily meet new regulatory requirements—especially with diversity and rural populations. • Reduce patient burden throughout the trial with ease of dosage dispensing. • Improved adherence reduces attrition, saving money when fewer patients need to be recruited.
Enhanced Data Insights	• Real-time objective compliance data replaces diaries and other subjective, unreliable data to eliminate variability coming from latent knowledge about patient adherence patterns. • Reduced risk of loss of critical data. • Improve the research team's understanding of patient behavior which helps them in two ways: 1. Improve clinical trial designs and develop more targeted drug interventions. 2. Empower team with real time data to manage interventions proactively. • Greater alignment of trial data with Real World Evidence to reduce financial and outcome risk in Phase 4.
Improve Patient Safety	• Ensure greater patient safety by eliminating sources of toxicity in medication management during trials.
Improved Clinical Trial Outcomes	• Improved medication adherence, reduced study attrition, and enhanced insights translate into better clinical trial outcomes, leading to improved drug efficacy, safety, and faster regulatory approvals. • This vastly improves the efficacy, efficiency, safety and long-term cost of clinical trials.

ROI	ROI Explanation
Reduced Development Costs In Four Ways	• Reduced patient recruitment costs come with lower attrition rates: 1% improvement in adherence reduces your required trial size by 2%--while maintaining its statistical significance. Since one-third of all failed trials occur because of insufficient enrollment, it behooves research teams to do whatever they can to keep patients in their trials. Knowledge of real time adherence is foundational to this effort. • Traceability of each dose by ECM system eases supply chain burdens and lowers dose tracking costs. • Traceability also provides transparency throughout the chain of custody, reducing waste. • IMC optimizes document reconciliation required by the FDA, saving a PI time and expense; the tracking front end is connected to the reporting backend—without manual labor associated with grafting data from diaries to the final documentation. This can offer huge savings at the end of the trial.
Can we calculate the potential ROI for using IMC services in our trial?	• Patients are only 50 to 65 percent adherent with their medication, and poor adherence reduces a clinical trial's ability to detect a treatment effect if one exists. The highest and best use of IMC's intelligent packaging solutions is early detection of non-adherence and correction through self-discovery, education and motivational counselling. • Modeling the interrelationship between statistical power, sample size and medication adherence shows that for every percent adherence is increased, a trial's sample size can be reduced by two percent while holding statistical power constant. With 35 to 50 percent non-adherence there's lots of room for improvement – and ROI.
Persistence and ECM	• ROI increases with trial size growing. • ROI increases with drug cost. • ROI is greater for drugs with high efficacy. • ROI is greater for drugs with critical dosing through improved clinical effect. • ROI is greater for drugs where side effects result from irregular dosing.
Use for ECM Adherence Data	• Confidence in one's data • Pre-trial screening, training for ITT studies • Detecting bias • REMS • Post hoc data adjustment • Post hoc stratification • Coaching
Intra-Trial Application	• Coaching • Highest and Best Use - Targeted education - Motivational counseling

Testimonials:
Value Creation In Their Own Words

Jenny Lin, MD

Internal Medicine
Mount Sinai
Professor, Internal Medicine
Icahn School of Medicine at Mount Sinai

Distinguish between what patients say they do vs. what they actually do.

Do researchers have a regulatory; ethical or legal responsibility in using tech platforms when they evaluate meds that have a timing or frequency dosage sensitivity fo them?

Donald Jones

Advisory Board, AstraZeneca
Operating Partner, Takada Digital Ventures
Chief Digital Officer
Scripps Research Translational Institute

The data we pulled from the trials impacted several commercial outcomes
as much as they helped us understand our outcomes and risk factors.

The evolution of how new technologies are developed: after we prove they work...we ask is it negligent not to use them?

Neels Groenewald, MD

Pediatric Anesthesiologist
Seattle Children's Hospital and The University of Washington

Patients have their own personalized risk factors and protective factors.
We need to individualize these meds to reduce patient risk. The only way I know how to do this is with IMC technology.

Retrospective recall and diaries: we've found the intelligent medication technology data is much more accurate. People are just not able to honestly report how much opioids they use.

First Use Case:
Seattle Children's Hospital

Challenge:

We don't know how adolescents use opiates following their surgeries. We need to understand how misuse pathways develop in the days, weeks and months after they have their procedures.

Purpose of Study:

We wanted to understand what happens after an adolescent gets his/her first opioid prescription. How he/she uses it, what factors drive use and how different usage patterns are identified.

Use of IMC and CertiScan:

Traceable Med-ic bottle caps were given to patients following their surgeries. Prescriptions: 1 dose every 4 hours, for 2 weeks. Supported by surveys conducted every 4 hours in conjunction with pain levels—to track stress, mood, physical activity and substance abuse.

Key Insights Gained From Strong Adherence Levels:

1. There's a large variability of need for meds among patients after surgery.

2. "One size fits all" for dosing does NOT work. We need to individualize dosage of pain meds to match the personalized risk factors of each patient to prevent over-dosing and reduce patient risk.

3. A large gap exists between how the PT thought they were using meds versus how they used them in real life.

4. We saved 33% of pill supply because adolescents don't follow strict protocol of dosage frequency.

5. Electronic tracking is far more accurate in evaluating adherence versus patient diaries and retrospective recall.

6. Protecting patients in the studies also protects the thousands, even millions, of patients using these meds after trial is finished.

7. We need more data on patient use to refine Standards Of Care for treating adolescents in managing their pain.

Seattle Children's
HOSPITAL · RESEARCH · FOUNDATION

Second Use Case:
Treatment for Hepatitis C Trial

Challenge:

Although Direct-Acting Antiviral (DAA) therapy is effective among People Who Inject Drugs (PWID), little is known about adherence, including factors associated with nonadherence and the impact of adherence on Sustained Virologic Response (SVR).

Purpose of Study:

Understand patient adherence to once-daily and twice-daily direct-acting antiviral therapy tor Hepatitis C Infection among people with recent injection drug use or current opioid agonist therapy. The majority of studies evaluating adherence among people receiving OAT or people with recent IDU have used imprecise methods for measuring adherence have heterogenous definitions of recenet IDU, are often single-center, and are limited by small sample sizes. No study has compared once-daily and twice-daily DAA therapy.

Use of IMC and CertiScan:

Participants in D3FEAT received ribavirin in pill bottles. All other study drugs were dosed weekly in electronic blister packs that recorded the date and time each dose was removed. In SIMPLIFY, the blister packs contained 1 tablet per day in a single blister. In D3FEAT, the blister packs contained 3 tablets in individual blisters for the morning dose and 1 tablet in a sinale blister for the evening dose. Participants received AUS$10 (or equivalent) to return each blister pack. Adherence was also measured by counting remaining pills in the returned blister packs (clinical pill count) and through self-reported adherence questionnaires every 4 weeks. Participants completed a self-administered questionnaire on a tablet computer at enrollment, at treatment commencement, and every fourth week during treatment.

GILEAD

Key Insights Gained From Strong Adherence Levels:

1. This study demonstrated high adherence to once and twice-daily DAA therapy among people with recent IDU or currently receiving OAT.

2. Nonadherence described did not impact treatment or outcomes, suggesting forgiveness to nonadherence.

3. These data are important to inform clinical guidelines, clinical management, and health policy, particularly in settings where restrictions for the reimbursement of DAA therapy for PWID are in place.

4. The use of electronic blister packs for adherence monitoring was a major strength of this study, allowing for detailed and accurate adherence measurement over time, providing a more precise estimate of the effect of time on nonadherence.

5. Blister pack measurement of adherence remains a more robust method of measuring adherence compared to dinical pill count or self-report.

Integration Capabilities

IMC's open architecture platform provides an ideal solution for clinical research organizations seeking to combine different technologies and software to support their clinical trials. The platform integrates seamlessly with other devices and software, enhancing the overall data collection and analysis process.

With the ability to integrate with other devices and software, IMC's platforms can collect data from different sources and formats, providing more in-depth insights into patient behavior and medication adherence. Data integration is a critical requirement in clinical trials because it eliminates data silos, leading to better data management, superior data quality, and more rational decision-making.

IMC's data pathway established with clinical research aggregators improves data collection, insights, and management during clinical trials. When integrated with data partners, IMC's solutions enable easy data capture, providing accurate information on patient adherence rates, drug efficacy, and regulatory compliance.

Most third party platforms support the integration of IMC's solutions—The Med-ic Smart Blister and the CertiScan Platform. The integration helps reduce manual errors and increase efficiencies in clinical trial data collection and analysis. Moreover, it simplifies analysis by providing a single centralized source of data that is HIPAA-compliant, secure, and accessible.

The combination of IMC's solutions and clinical research aggregators ensures that clinical researchers can generate timely and accurate reports based on real-time data insights, enabling them to make informed decisions, improve patient outcomes, and optimize overall trial performance.

Additionally, IMC is committed to integrating artificial intelligence into its platform to provide more powerful insights and improve medication adherence management during clinical trials. Integrating AI-enabled solutions will enable real-time analysis of patient data, improving decision-making, predicting patient behaviors, and providing personalized treatment approaches.

By leveraging artificial intelligence, clinicians can gain insight into the impact of patient characteristics, such as age, race, and ethnicity, on medication adherence rates, allowing them to individualize treatment plans further. Real-time analysis of adherence data can enhance patient outcomes and clinical trial outcomes. Furthermore, these insights assist in developing new approaches to improve adherence and drive medication optimization.

IMC's aggressive approach to integrating artificial intelligence enables sponsors to elevate their understanding of patient outcomes while still managing the complex tasks associated with trials in a more efficient manner. With an end-to-end adherence data solution, IMC enables analysis of large data sets to support improved outcomes.

In conclusion, IMC's groundbreaking efforts towards integrating artificial intelligence will allow more powerful insights and medication adherence management for clinical trials. By making data-driven decisions, clinicians can provide patients with personalized care while delivering efficacy and driving medication optimization further.

Summary

With billions of dollars spent in clinical trials, the one area that's often overlooked but crucial to get right is the inclusion of electronic monitoring tools that capture patient adherence in real time. They are foundational to a trial's success because, without the objective data generated from these tools, a trial team is making educated guesses that put patients at risk, add unnecessary costs and jeopardize the accuracy of findings in their clinical trial.

The IMC-CertiScan system provides the missing link in trial management: real-time, objective data that establishes Adherence Intelligence, which drives all data-driven decisions throughout the life of the trial and ensuing research efforts. Several key benefits for the sponsor and CRO:

- Remote monitoring supports your access to hard-to-reach populations who are now required by FDA protocols.
- Real-time reporting empowers your team to take proactive measures when they see adherence levels drop. These measures support patient retention and help sponsors mitigate costs of unnecessary patient recruitment. Patient safety may be enhanced as well.
- The marriage of patient profiles with 100% accurate adherence data enables patently clear insights into the efficacy of a new medication.
- Metadata from the trial can be applied with greater accuracy to ensuing research, where each phase supports the collective value chain within a drug's journey for FDA approval.
- The presence of electronic ID tags within the ECM network streamlines supply chain and documentation activities, saving hundreds of hours of personnel time and reducing waste.
- These activities may help sponsors reach their statistical endpoints sooner, to facilitate FDA approval and generate revenues more quickly.

Appendix:
A Glossary of Key Terms

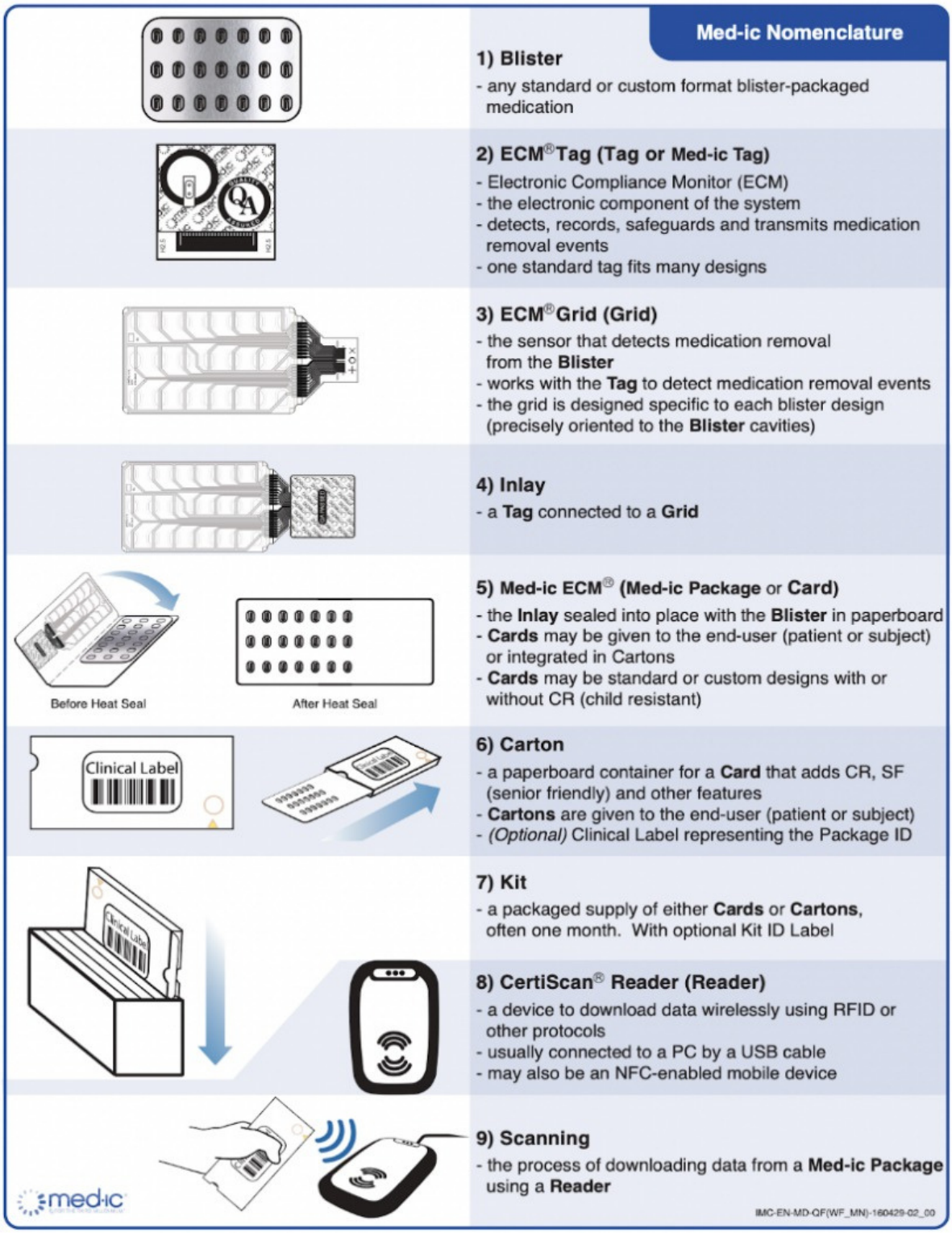

Figure 6

Appendix Continued:
CertiScan Screenshots

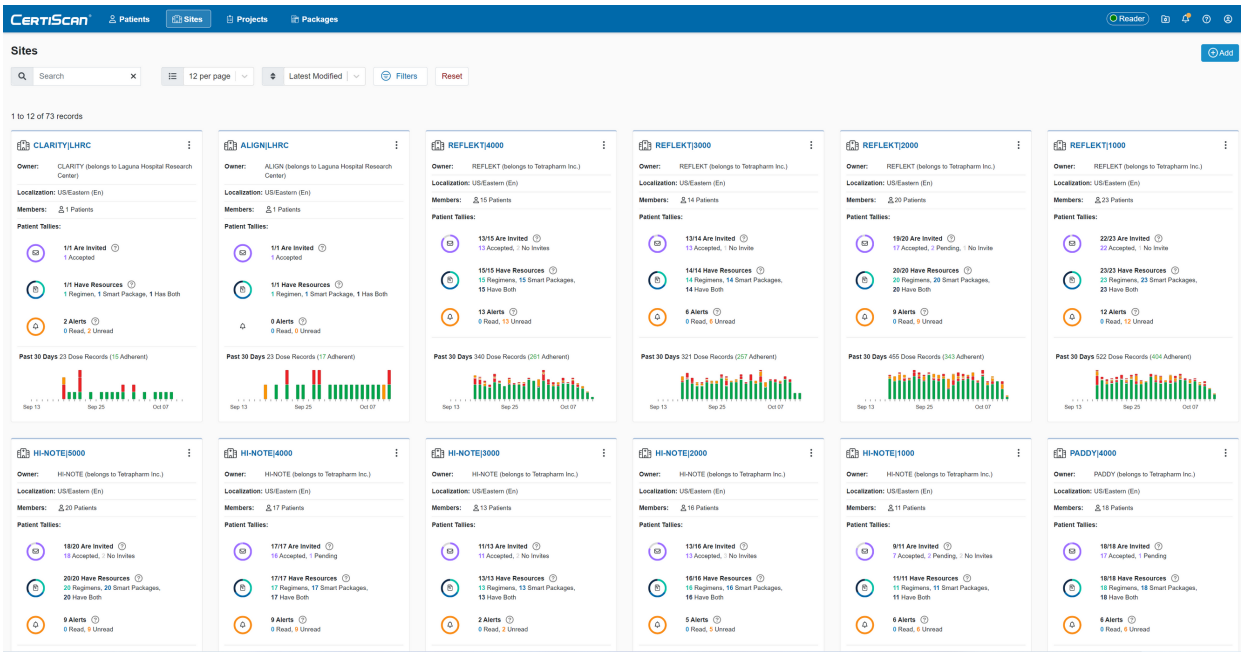

Figure 7

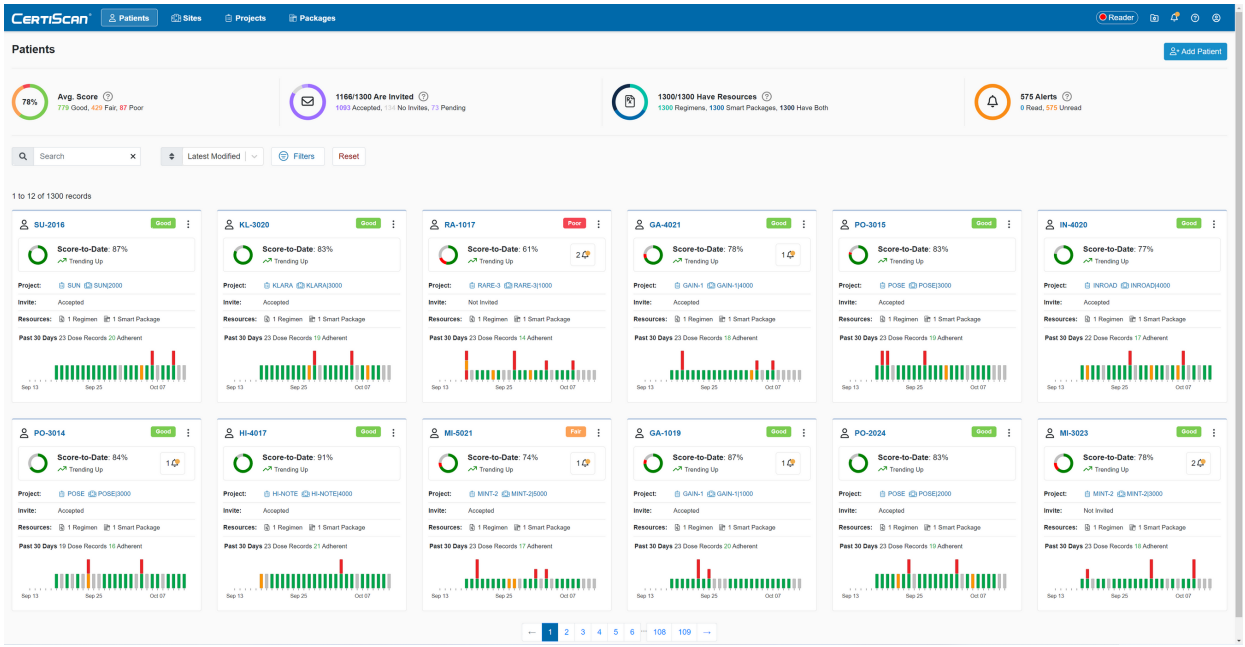

Figure 8

Appendix Continued:
CertiScan Screenshots

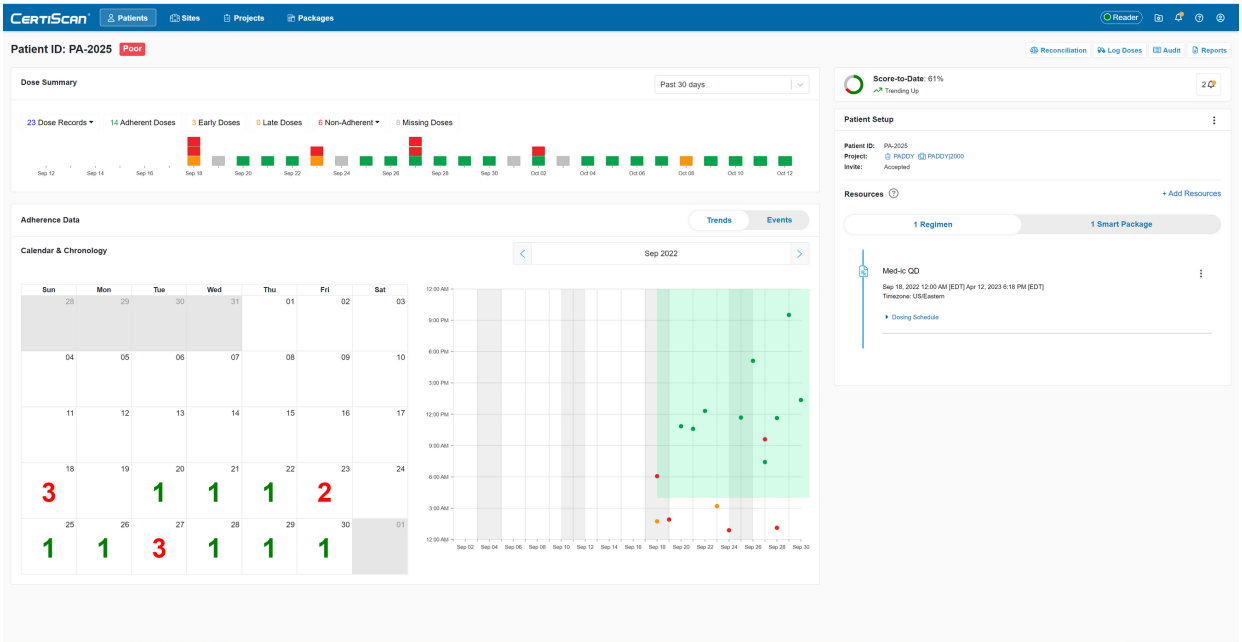

Figure 9

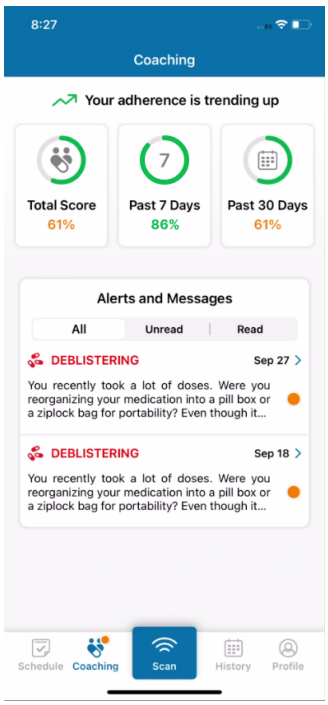

Figure 10

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