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AI and Wearables Bring New Data and Analytics to Clinical Trials

The Intel® Pharma Analytics Platform offers continuous, remote patient monitoring and artificial intelligence to help streamline clinical trials, reduce costs, and deliver fresh insights for drug development

This solution brief describes how to solve business and clinical challenges through investment in innovative technologies.

If you are responsible for...

- **Digital health strategy:**
  You will better understand how remote patient monitoring and an artificial intelligence solution will enable you to capture value from advanced analytics and enhance your mobile digital health strategies.

- **Technology decisions:**
  You will learn how remote patient monitoring and an artificial intelligence solution works to deliver IT and business value.

Executive Summary

Clinical trials, which seek to prove the safety and efficacy of new treatments through controlled testing on patients, are fraught with challenges that drive up R&D costs and slow the delivery of promising new treatments.

The Intel® Pharma Analytics Platform is an edge-to-cloud artificial intelligence (AI) solution that helps improve clinical trials. The platform uses remote monitoring to efficiently capture continuous clinical data from sensor-equipped wearable devices and applies machine learning techniques to develop objective measures for assessing symptoms and quantifying the impact of therapies. By using the platform, pharma companies can:

- Gather objective, high-quality, data-rich sensory data such as skin temperature and movement activity levels as participants live their lives
- Apply sophisticated analytics methods to assess patient symptoms and identify subtle patterns
- Get real-time information about protocol adherence while helping patients manage medication, perform structured tests, and report symptoms
- Establish novel clinical end-points that supplement subjective, manually collected data with automated, objective data from devices

These capabilities can help address objectives such as reducing operational costs for clinical trials, increasing patient adherence, and improving the quality of the resulting evidence. This approach offers new tools to help inspire insights and accelerate drug development.

End-to-End, Extensible Intel® Pharma Analytics Platform Solution

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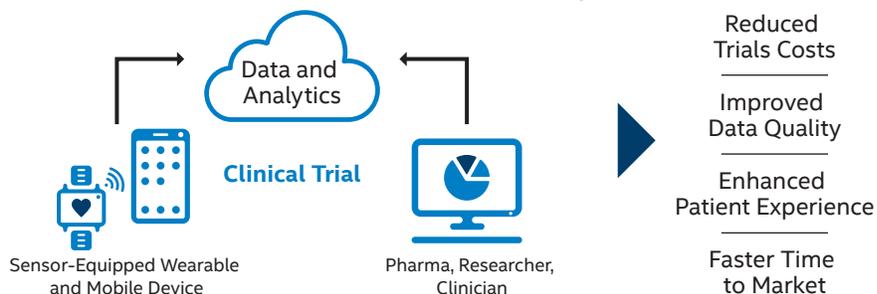Senior Health and Life Sciences Solutions
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Figure 1. With the Intel® Pharma Analytics Platform, companies and researchers improve clinical trials by capturing data from sensor-equipped wearable devices and a smartphone app, and streaming it to a secure cloud for advanced analytics.

Business Challenge: Improve Clinical Trials

Developing prescription drugs is a costly, high-risk undertaking. Each approved prescription drug represents an average investment of 10 years and USD 2.56 billion, with post-approval R&D adding another USD 312 million.[1] Fewer than 10 percent of compounds that enter clinical trials are ever approved.[2]

These factors contribute to higher drug prices while pushing pharma companies to concentrate on the most common diseases. The same issues also tend to slow the flow of groundbreaking medications, reducing treatment choices for patients with rarer conditions.

Clinical trials account for a staggering 40 percent of the pharma industry's research budget.[3] Demonstrating a new treatment's efficacy can be particularly challenging for neurological and other diseases where symptoms vary widely, changes are subtle, and disease progression can be hard to assess. To determine efficacy, researchers gather evidence through clinic visits, where patients report on their symptoms, or paper diaries, in which patients record their medication regimen, symptoms, and observations. These approaches burden patients, contributing to the possibility of dropouts. In addition, the resulting evidence is subjective and often grows spotty during lengthy trials, providing a limited basis for analytics and decision making. And because patients may project a positive outcome during clinic visits, their reports may inadvertently produce biased results.

Remote monitoring with wearable devices offers new opportunities to advance clinical trials. By collecting data such as patients' movement activity, heart rate, and glucose levels, these devices can help produce consistent, objective evidence of the actual disease state and a treatment's impact. Kaiser Associates conducted a study for Intel projecting that up to 70 percent of clinical trials will incorporate wearable sensors by 2025. Leaders in the pharmaceutical, contract research, and medical device industries reported that they expect wearable devices to help reduce clinical trials costs, deliver higher-quality data, and speed time-to-results.[4]

To achieve that value, pharmaceutical companies must capture, manage, and analyze vast amounts of data from wearables. A typical phase 2 trial that runs for 6 months with 100 patients would generate over 200 billion data points. Developing objective criteria for assessing a treatment's impact is a crucial challenge and requires expertise as well as domain-specific experience.

TRANSFORMING TRIALS

70% of clinical trials will use wearables by 2025.[5]

Comprehensive AI Platform for Continuous Remote Monitoring Using Sensors and Wearable Devices

The Intel® Pharma Analytics Platform is a scalable platform as a service for:

- Capturing new kinds of data from clinical trials subjects using sensors, wearables, and smartphone apps
- Collecting electronic dairies and patient-reported outcomes (PROs) using a smartphone app
- Transmitting the data to a secured cloud infrastructure for storage and analysis
- Applying machine learning and other AI methods to analyze the data and quantify qualities such as medication efficacy or dose response

These capabilities address critical aspects of clinical trials:

- **Objective, high-quality data.** Teams can measure and collect data including skin temperature, sweat detection, heart rate, blood pressure, glucose levels, movement activity levels, and movement acceleration both during the day and while sleeping. Data can be collected continuously in real time as patients live their lives.

- **Patient engagement.** A mobile application allows data collection through questionnaires, digital diaries, and home assessment tasks. Patients can get feedback on certain symptoms and manage their medication intake, as well as track and share other information in accordance with the study protocol. Gamification strategies help patients stay engaged and motivated.

- **Trials management.** Pharma companies and contract research organizations (CROs) can collect data more efficiently. Trial administrators and CROs can track adherence in real-time, intervening to encourage compliance with treatment protocols. Clinical teams monitor patients for adverse events and intervene to help improve care and reduce the number of dropouts.

- **Analytic insights.** The platform has a rich machine learning library and exposes tools and capabilities that enable researchers and data scientists to query the data and run machine learning algorithms securely and at scale on the data collected. In addition, Intel offers an analytics service for data analysis and clinical end-points development by Intel's machine learning specialists.

Intel collaborated with the Michael J. Fox Foundation (MJFF) for Parkinson's Research, the world's largest non-profit funder of research into Parkinson's, as the company developed the Intel Pharma Analytics Platform. The platform has been used in over a dozen clinical trials, comprising more than 1.2 million hours of data collection with over 1,000 patients.

Among ongoing trials, Teva Pharmaceutical Industries Ltd* is using the Intel® platform in the largest mobile health (mHealth) Huntington Disease (HD) study to date. The global trial collects data from nearly 100 HD patients over six

months, with the intent of generating algorithms to quantify various HD motor disorder symptoms associated with the disease. Patients are monitored continuously in their home environments and can carry out predefined structured tests.[6] The Intel platform has also been used in population, concept validation and research studies with the Scripps Research Institute in California, Mount Sinai Health hospital in New York City, the Radboud University in the Netherlands, and other research institutes.

Solution Value: Improving Clinical Trials and the Bottom Line

The Intel Pharma Analytics Platform provides benefits for pharmaceutical companies seeking to speed and simplify clinical trials, reduce trials costs, and gather more objective evidence.

By transitioning from PROs and subjective scales to automatic collection of consistent, unbiased, high-quality sensor data and quantitative measurement scales, pharma researchers can measure changes with greater accuracy and precision. Researchers can use this objective evidence to assess and demonstrate a new treatment's clinical efficacy, effectiveness, safety, and side effects.

Remote monitoring data produces a powerful foundation for analysis that can deepen insights into how a drug affects symptom progression and quality of life. Analytics teams can combine de-identified trials data with information from genomic, lifestyle, and other sources to explore new possibilities for future treatment breakthroughs. The platform facilitates this analysis through a data analytics service developed by Intel data science specialists with expertise in signal processing and machine learning as well as significant experience in developing clinical end-points and objective measurements for movement disorders.

Remote data collection has the potential to help reduce the frequency of clinic visits and simplify the tasks clinicians and patients must perform during each visit. These changes can help lower site costs while minimizing the burdens on patients, easing patient recruitment, and increasing retention. The solution's real-time engagement and communication capabilities may help increase adherence and compliance, further improving patient retention. These outcomes apply to clinical trials as they exist today while facilitating the industry's movement toward virtual trials.

By delivering practical value to patients, the solution's capabilities can help generate loyalty that extends beyond the trial itself. Patients may gain a clearer picture of their health, an increased sense of control, and a feeling of pride in contributing to important research. Advocacy groups, patients, and families may feel more loyal to drug companies that demonstrate their commitment to advanced research and innovative technologies.

Pharma leaders expect these changes to help accelerate time-to-market for new drugs and possibly reduce costs. By producing high-quality data and reducing dropouts, trials

CAPTURING VALUE FROM WEARABLES

Researchers asked 80 pharma leaders for their #1 anticipated benefit from wearables:[7]

58% Better Data

33% Faster Results

10% Lower Trials Costs
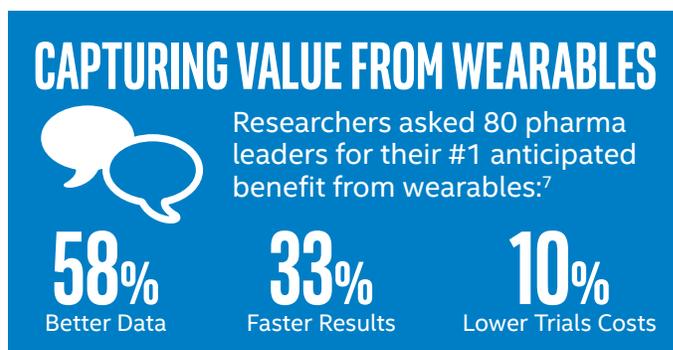
leaders may be able to conduct shorter trials with fewer enrolled participants. With advanced analytics and larger, more diverse data sources, analysts may generate more robust evidence for presentation to regulatory agencies. Pharmaceutical innovators may also solidify their scientific understanding earlier in the development cycle, leading to more efficient, evidence-based allocation of resources.[8]

Solution Architecture: Pharma Analytics for Wearable Technologies

As an end-to-end solution powered by Intel's AI expertise and technologies, the Intel Pharma Analytics Platform offers a comprehensive solution for capturing value for clinical trials from data generated by wearables. The solution integrates one or more wearable devices, a dedicated phone application with patient interaction, and a back-end cloud solution that stores big data and enables the development of novel algorithms. The configurable mobile app runs on iOS* and Android* smartphones. Figure 2 provides an overview of the solution architecture.

The solution is built to scale, allowing researchers to collect, store, and process data from thousands of patients. Once data is streamed to the cloud, scientists and researchers can run complex algorithms, reports, and queries to gain novel insights.

Algorithms developed by Intel can run on both the smartphone and in the cloud, and reflect Intel's deep analytics experience with data collected from mobile devices in healthcare. Initial symptom quantification algorithms focus on neuromuscular diseases, and the open architecture makes the solution extensible to other diseases, use cases, and data source types.

To manage and analyze massive volumes of streaming sensor data, Intel created a big data analytics platform based on Cloudera* Distribution for Hadoop*, an open source distribution of Apache* Hadoop, and other distributed analytics software. The solution runs on cloud-based infrastructure at Amazon Web Services*, taking advantage of the Intel® Xeon® processor E7 v4 family for analytics and storage management and the Intel® Xeon® processor E5 v4 family for the web API and data ingestion. Cloudera software and Intel® Solid State Drives (Intel® SSDs) deliver high performance for large data volumes. Intel SSDs also allow for enhancing privacy and security through full-disk encryption.
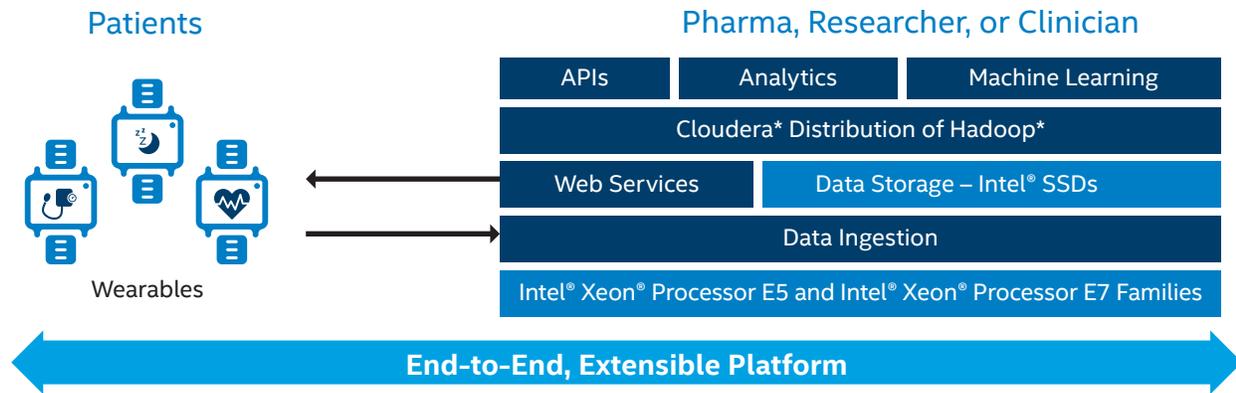
Figure 2. As an edge-to-cloud artificial intelligence platform, the Intel® Pharma Analytics Platform enables clinical trials teams to collect a wide range of data, design innovative algorithms, and apply objective measures for quantifying the effect of a therapy.

Conclusion

Building on Intel's AI and analytics leadership, the Intel Pharma Analytics Platform provides an extensible, edge-to-cloud AI platform for collecting and analyzing continuous, objective data from patients enrolled in clinical trials. The solution has been applied in dozens of trials in collaboration with leading pharmaceutical companies, medical centers, and research institutions. By augmenting subjective, patient-reported outcomes with sensor data collection and applying machine learning and other AI methodologies, pharma leaders can capitalize on cutting-edge technology innovation designed to help reduce trials costs, improve data quality, increase patient compliance, and ultimately identify treatment efficacy. These changes may also help identify promising new approaches and accelerate the drug approval pipeline, bringing innovative treatments to patients more rapidly.

Find the solution that is right for your organization. Contact your Intel representative or visit **intel.com/healthcare**.

Learn More
- Intel® Pharma Analytics Platform Animation
- Intel and the Michael J. Fox Foundation: Using Wearable Technology to Advance Parkinson's Research Paper
- Intel and Teva Pharmaceuticals: Implementation and Validation of a Biometric Solution for Remote Monitoring of Motor Symptoms in Patients with Huntington's Disease in a Phase II Clinical Trial Paper
- Intel Xeon processors
- Intel SSDs
- Cloudera Enterprise Data Hub
- Amazon Web Services and Intel

Solutions Proven By Your Peers

Intel Solutions Architects are technology experts who work with the world's largest and most successful companies to design business solutions that solve pressing business challenges. These solutions are based on real-world experience gathered from customers who have successfully tested, piloted, and/or deployed these solutions in specific business use cases. Solutions architects and technology experts for this solution brief are listed on the front cover.

Intel IT is focused on using cutting-edge technology to create business value and act as a catalyst for organizational transformation. As part of its commitment to driving industrywide innovation, Intel IT has built its own competency center for data analytics. This team is tasked with optimizing Intel's internal processes through digital innovation, for which the current focus is artificial intelligence (AI) and machine learning. The center then repurposes the technology to create products and solutions for use by its ecosystem and customers.