intel®

IT@INTEL

Transforming Clinical Trials with the Power of AI

Clinical Trial Subject Sensor Data

Intel® Pharma Analytics Platform

Insights that benefit:
- Pharmaceutical companies
- Clinicians and researchers
- Patients

Chen Admati
Head of Intel® Pharma
Analytics Platform,
Advanced Analytics, Intel IT

Yonatan Dolan
Business Development and
Strategy, Intel® Pharma
Analytics Platform,
Advanced Analytics, Intel IT
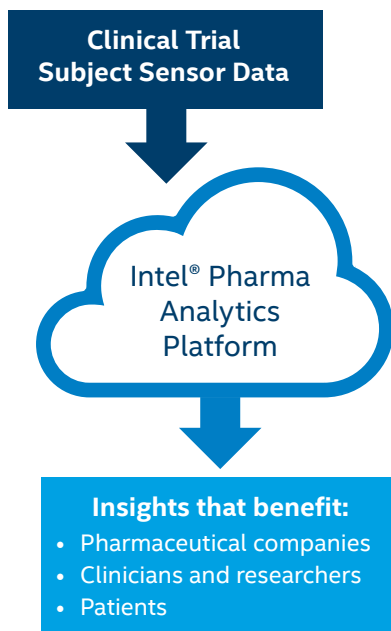
Executive Overview

Clinical trials, which seek to validate the safety and efficacy of new treatments through controlled testing on patients, are fraught with challenges that drive up research and development (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 enables remote monitoring to continuously capture clinical data from study subjects using a variety of sensors, including wearable devices. It applies advanced machine-learning techniques to objectively measure symptoms and quantify the impact of therapies.

Building on Intel IT's AI and analytics experience, trials that use the Intel Pharma Analytics Platform can:

- Capture de-identified, objective, high-quality sensory data through wearables and other devices
- Obtain real-time information about protocol adherence while helping patients manage medication, perform structured tests, and report symptoms
- Utilize smartphone applications to collect electronic diaries and patient-reported outcomes (PROs)
- Transmit the anonymized data to a secured cloud infrastructure for storage and analysis
- Apply machine learning and other AI methods to objectively assess and quantify the severity of symptoms and measure the impact of therapies, such as medication efficacy or dose response

The Intel Pharma Analytics Platform provides benefits for pharmaceutical companies seeking to speed and simplify clinical trials, reduce trial costs, and gather more objective evidence by automatically collecting consistent, unbiased data, remotely monitoring for data analysis, and delivering an improved patient experience. It also helps accelerate time to market (TTM) for new drugs by producing high-quality data and increasing patient retention, leading to shorter trials.

Contents

Acronyms

AI	artificial intelligence
CRO	contract research organization
HD	Huntington's Disease
PRO	patient-reported outcome
TTM	time to market

Clinical Trial Timeline

Research and Development
USD 2.9 billion[1]

11 years

Clinical Trials
USD 1.1 billion[1]

6.6 years

Approval
~14% of drugs that enter
clinical trials gain approval[2]
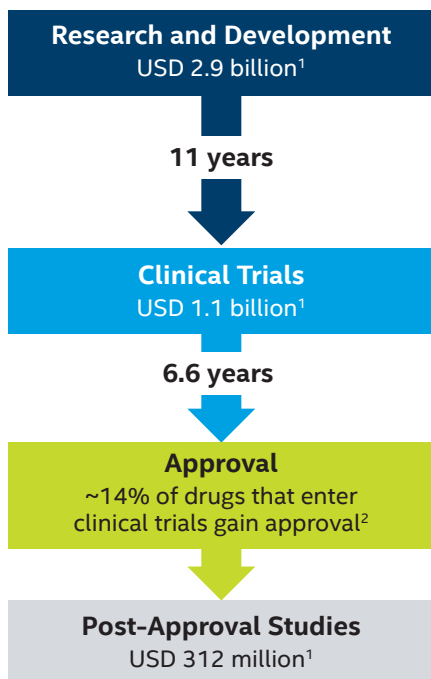
Post-Approval Studies
USD 312 million[1]

Figure 1. Drug research and development costs USD 2.9 billion over 11 years. Clinical trials can cost up to USD 1.1 billion over 6.6 years. Only 14 percent reach approval. Post-approval studies cost USD 312 million.

Business Challenge

Developing prescription drugs is a costly, high-risk undertaking. Each approved prescription drug represents an average research and development (R&D) investment of USD 2.9 billion over 11 years, while clinical trials can cost an average of USD 1.1 billion over 6.6 years[1]. Ultimately, only 14 percent of drugs that enter clinical trials are ever approved.[2] Post-approval studies cost USD 312 million[1] (see Figure 1).

These factors contribute to higher drug prices while pushing pharmaceutical 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 pharmaceutical 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 use 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 becomes less accurate during lengthy trials, providing a limited basis for analytics and decision making. Due to "white coat syndrome," patients may display abnormal behavior during clinic visits, and their reports may inadvertently produce biased results.[4]

Remote monitoring using wearables and other devices and sensors 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 sensors by 2025. Leaders in the pharmaceutical, contract research, and medical device industries reported that they expect these devices to help reduce clinical trials costs, deliver higher-quality data, and speed time to results.[5]

To achieve that value, pharmaceutical companies must capture, manage, and analyze vast amounts of data from devices. 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.

Solution

The Intel® Pharma Analytics Platform is a scalable platform-as-a-service (PaaS) solution that captures new kinds of data from clinical trials subjects using sensors, wearables, smartphone apps, and other devices. It passively collects electronic dairies and patient-reported outcomes (PROs) as well as sensorial data, then transmits the de-identified data to a secured cloud infrastructure for storage and analysis (see Figure 2). The platform uses machine learning and other AI methods to analyze the data and quantify sensor information that has been identified as evidence of efficacy in the study protocol. It can collect data from multiple sensors to provide a broader understanding of patient health across a wide spectrum of needs.

The Intel Pharma Analytics Platform's capabilities address critical aspects of clinical trials, including:

- **Objective, high-quality data**. Clinical 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.** Sensors passively collect patient-centric data without requiring patient interaction. A mobile application also 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.** Pharmaceutical 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.
- **Analytics 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.

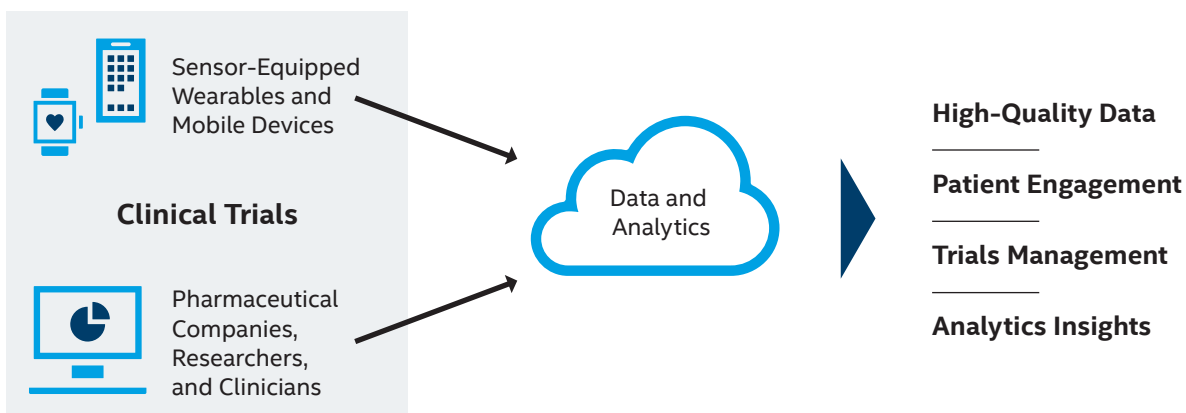## End-to-End, Extensible Intel® Pharma Analytics Platform Solution

Figure 2. With the Intel® Pharma Analytics Platform, companies and researchers improve clinical trials by capturing data from sensor-equipped devices and a smartphone app, and stream it to a secure cloud for advanced analytics.

Benefits

The Intel Pharma Analytics Platform helps pharmaceutical companies speed and simplify clinical trials, reduce trial costs, and gather more objective evidence. It provides the following benefits:

- **Greater accuracy.** With automatic collection of consistent, unbiased, high-quality sensor data and quantitative measurement scales, pharmaceutical companies can measure changes with greater accuracy. Researchers can use this objective evidence to assess and demonstrate a new treatment's clinical efficacy, safety, and side effects.

- **Deeper insights.** 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 anonymized trial data with information from genomic, lifestyle, and other sources to explore new possibilities for future treatment breakthroughs. The platform was developed by data science specialists who have expertise in signal processing and machine learning, as well as experience in developing clinical end-points and various objective measurements.

- **Increased patient retention.** Remote data collection can help reduce the frequency of clinic visits and simplify the tasks clinicians and patients must perform. Reducing the burden on patients helps increase recruitment, compliance, and retention. Real-time communication can also improve compliance and help facilitate the industry's movement toward virtual clinical trials.

- **Improved patient engagement.** By delivering practical value to patients, the solution can improve 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 be more loyal to drug companies that demonstrate their commitment to advanced research and innovative technologies.

- **Accelerated time to market (TTM).** By producing high-quality data and reducing the dropout rate, trial leaders may be able to conduct shorter trials with fewer enrolled participants. With advanced analytics and larger, more diverse data sources, analysts can generate more robust evidence for regulatory agencies. Pharmaceutical innovators may also solidify their scientific understanding earlier in the development cycle, leading to more efficient, evidence-based allocation of resources.[6]

Use Cases

Intel IT teamed up with the Michael J. Fox Foundation (MJFF) to improve research and treatment associated with Parkinson's disease, which included a multiphase research study to gain insights from patient data collected with wearable and mobile technologies. The result of this study helped build the Intel Pharma Analytics Platform, which has been used in over a dozen clinical trials, comprising more than 1.5 million hours of data collection with over 1,000 patients.

Among trials, Teva Pharmaceutical Industries Ltd has used the platform in the largest mobile health (mHealth) Huntington's Disease (HD) study to-date. This global trial collected data from HD patients for over six months, with the intent to generate algorithms that quantify various HD motor disorder symptoms associated with the disease. Patients were monitored continuously in their homes and carried out predefined structured tests.[7] The Intel Pharma Analytics 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.

ICON plc, a global provider of drug development solutions and services to the pharmaceutical, biotechnology, and medical device industries, successfully conducted a feasibility study using the Intel Pharma Analytics Platform. ICON plc focused on respiratory conditions such as chronic obstructive pulmonary disease (COPD) using a two-center, non-interventional study with 20 subjects. The study objective was to use the platform to demonstrate the ability to capture biometric data to generate a digital biomarker to monitor respiratory patients. Data was collected from six sensors types, such as a smart spirometer, contact-free sleep monitoring, and a wearable device.

Architecture

The Intel Pharma Analytics Platform is an end-to-end solution powered by Intel® AI technology that integrates one or more devices, a dedicated mobile application with patient interaction, and a cloud solution for storing and analyzing big data. The configurable mobile app is compatible with iOS* and Android* smartphones. It offers a high degree of flexible configuration through modules, such as medication regimes, questionnaires, and structured tests. Each module can be configured to collect specific information. For example, the researcher or clinician can choose which structured test for the subject to perform (both in-clinic and at home), the frequency, and what times or events trigger them. See Figure 3 for an overview of the solution architecture.

Intel Pharma Analytics Platform is scalable, allowing researchers to collect, store, and process data from thousands of patients. Once data is transmitted to the cloud, scientists and researchers can perform complex algorithms, reports, and queries to gain new insights. Initial symptom quantification algorithms focus on neuromuscular diseases, and the open architecture is extensible to other diseases, use cases, and data source types.

To manage and analyze massive volumes of sensor data, Intel created a big data analytics platform using distributed analytics software. The solution runs on cloud-based infrastructure at Amazon Web Services* (AWS*), taking advantage of the latest generation of Intel® Xeon® processors for analytics and storage management and the Intel® Xeon® processor E7 family for the web API and data ingestion. 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.

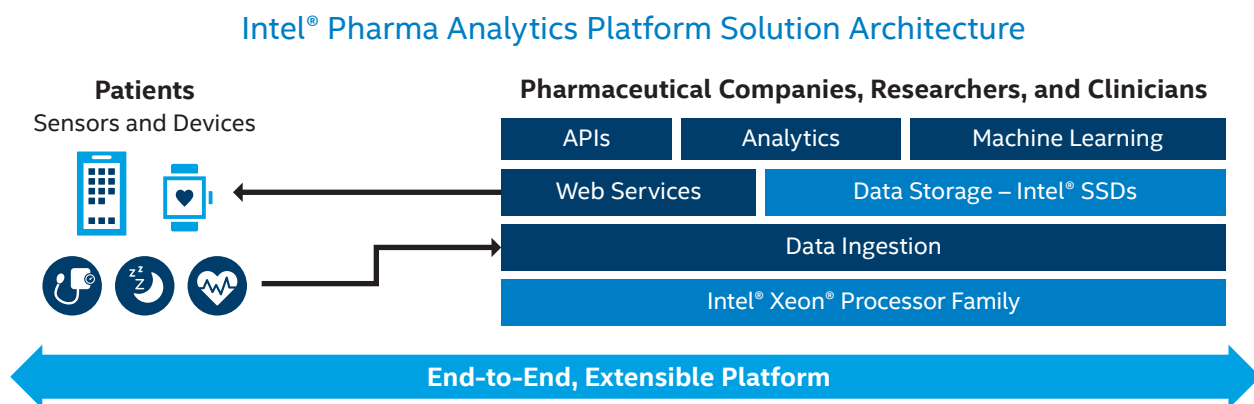## Intel® Pharma Analytics Platform Solution Architecture

Figure 3. The Intel® Pharma Analytics Platform enables clinical trial teams to collect a wide range of data, design innovative algorithms, and apply objective measures for quantifying the effects of therapy.

Conclusion

Building on Intel's AI and analytics experience, 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. In collaboration with leading pharmaceutical companies, medical centers, research institutions, and CROs, the solution has been used in dozens of trials. By augmenting subjective PROs with sensor data collection and applying machine learning and other AI methodologies, pharmaceutical leaders can capitalize on cutting-edge technology innovation designed to help reduce trials costs, improve data quality, increase patient compliance and engagement, and ultimately identify treatment efficacy. These changes may also help identify promising new approaches and accelerate TTM, bringing innovative treatments to patients more rapidly.

For more information on Intel IT best practices, visit intel.com/healthcare.

1 Liason Technologies, "What is the Cost of Drug Development?" May 2, 2017.

2 Center Watch, "New MIT Study Puts Clinical Research Success Rate to 14 Percent," February 5, 2018.

3 Aidan Nuttall, "RDP Clinical Outsourcing: Considerations for Improving Patient Recruitment into Clinical Trials," March 23, 2012.

4 For more information about white coat syndrome, see "White coat hypertension (and white coat effect)."

5, 6 Kaiser Associates, Enterprise-purchased Wearables and Consumer Health Data Platform. May 2016. Confidential research conducted for Intel.

7 Spyros Papapetropoulos, MD, et al, "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." Published April 17, 2017.