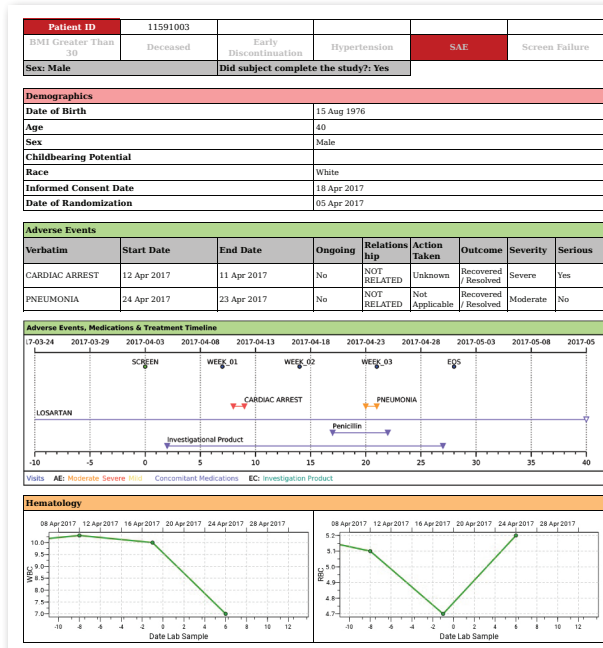# Medidata Edge Patient Profiles
Improving Data Quality, One Patient at a Time

Sponsors of clinical investigations are required to provide oversight to ensure adequate protection of the rights, welfare, and safety of human subjects and the quality of the clinical trial data submitted to FDA[1]. Patient safety and data quality are of paramount importance to the success of a clinical trial and it is imperative that they are monitored throughout the drug development life-cycle.

Various life sciences professionals play a key role in ensuring patient safety and data quality. This highlights a significant need for patient-relevant data, from multiple sources, all available in one place and represented in a manner that conveys the entire story of a patient.

Introducing Medidata Edge Patient Profiles, a solution that redefines patient oversight by leveraging the industry's most advanced profile designs to enable safety and medical reviews of patient-level critical data. Powered by the Medidata Enterprise Data Store (MEDS), Patient Profiles utilizes aggregated, mastered, and integrated data, in a timely manner, from multiple study-specific sources to provide a holistic view of the patient.

Inside a Medidata Edge Patient Profile

Set conditions to highlight and flag important patients & events.

Show timeline of imporant events.

Customize to focus on areas of importance.

SEE HOW MEDIDATA EDGE PATIENT PROFILES CAN MEET YOUR INDIVIDUAL AND ORGANIZATIONAL NEEDS FOR PATIENT SAFETY AND DATA QUALITY

Medical/Safety Monitor
Use Patient Profiles to help make accurate clinical judgements and offer medical input for certain flags or patient conditions that elicit a review

Data Manager
Use Patient Profiles to monitor and enhance the quality of data gathered in the study

Clinical Research Associate (CRA)
Use Patient Profiles to see if data about Adverse Events, Concomitant Medications and other patient-level critical data has been reported accurately

Medical Writer
Use Patient Profiles to augment patient narratives needed for agency submissions

Pharmacovigilance
Use Patient Profiles to drill down into patient-level data for patients of interest to minimize risk of any harm to patients

Data and Safety Monitoring Boards & Adjudication Committees
Use Patient Profiles to ensure studies are well run, patients are safe and are being cared for in accordance with prevailing clinical safety standards

1   21 CFR part 312, subpart D generally (Responsibilities of Sponsors and Investigators) and 21 CFR part 812, subpart C generally (Responsibilities of Sponsors).

Why Medidata Edge Patient Profiles

Patient Profiles: Redefining Patient Oversight

Enable better patient safety and data quality with a holistic overview of patient data

Visualize the overall, aggregated patient story to enable safety and medical reviews of patient level critical data

Make informed and timely decisions with deeper clinical and medical insights

Use color coded and highlighted tabular and graphical data in profile designs that you can build/modify without any programming for faster and more accurate case reviews

Augment patient narratives with customized patient profiles for key patients and events

Design, populate and export a completed Patient Profiles in PDF format and share as needed

The Medidata Difference in Redefining Patient Oversight

1
Create patient stories that speak to you using a fit-for-purpose patient profiles tool, without using programming level resources

2
Visualize actual study data while designing profiles to see how the design is taking shape

3
Setup patient profiles with easy to use drag-and-drop features and view up-to-date profiles with easy click of a button data refreshes

4
View patient-level data chronologically aligned with visit dates

5
Set conditions to highlight and flag important patients and events

6
Simply export as a PDF and share as needed

> **"The Patient Profiles tool helped resolve medical cases more efficiently — reducing timelines while also ensuring data quality."**
>
> Executive Director, Clinical Operations, Mid-Sized Pharmaceutical Company

SUCCESS STORY

A top 10 CRO used Medidata Edge Patient Profiles and reported an 83% reduction in case review time by Medical Monitors, from 2-3 hours to 20-30 minutes per case.

About Medidata Solutions

Medidata is leading the digital transformation of life sciences with the world's most-used platform for clinical development, commercial and real-world data. Powered by artificial intelligence and delivered by #1 ranked industry experts, the Intelligent Platform for Life Sciences helps pharmaceutical, biotech, medical device companies and academic researchers accelerate value, minimize risk and optimize outcomes. Medidata serves more than 1,000 customers and partners worldwide and empowers more than 100,000 certified users every day to create hope for millions of patients. Discover the future of life sciences: **www.mdsol.com**

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Cloud-based clinical research solutions | Innovative technology | Data-driven analytics
Reduced costs | Improved time to market | Faster decisions | Minimized risk