

# STRENGTHENING COMPLIANCE AND MITIGATING LIABILITY FOR MEDICAL DEVICE MANUFACTURERS

## THE OPPORTUNITY

Tracking Precisely How Data is Captured, Used and Secured Over the Data Lifecycle

Within the medical device industry, two obvious examples come to mind illustrating the importance of data chain of custody. First, given the sensitive nature of personal health data, **protecting patient privacy** is of critical importance. Second, to save human lives and **reduce product liability risks**, the data associated with a device not performing as designed must be traceable across that device's lifespan in a timely and rigorous manner.

## DATA CHAIN OF CUSTODY is Essential to Medical Device Manufacturers

In 2019, data breaches cost the healthcare industry

**\$4B**

Following a major recall, manufacturers experience up to a

**10%** decrease in share prices<sup>2</sup>

In the last three years, a data breach was experienced by

**93%** of healthcare organizations<sup>3</sup>



By 2026, the implantable device industry is expected to grow an estimated

**\$153B**<sup>4</sup>

Since 2016, the amount of data healthcare organizations manage has increased by

**900%**<sup>5</sup>

## ESTABLISHING YOUR DATA CHAIN OF CUSTODY

**70%**



of the top 100 global manufacturers run on Cloudera

**200**



of the world's leading manufacturing companies rely on Cloudera

Cloudera's real-time streaming analytics platform helps medical device manufacturers easily capture, combine, secure, and drive insights on data feeds from device sensors, bio-monitors, and other connected IoT devices. Our solutions enable medical device manufacturers to comply with health and data regulations, protecting patients' health and privacy while mitigating potential liabilities.

**In other words, Cloudera can help turn challenges into opportunities and risks into rewards.**

**Click here** for more information on the importance of establishing a strong Data Chain of Custody.

<sup>1</sup> Davis, Jessica. "Data Breaches Will Cost Healthcare \$4B in 2019, Threats Outpace Tech." *HealthITSecurity*, 5 Nov. 2019, healthitsecurity.com/news/data-breaches-will-cost-healthcare-4b-in-2019-threats-outpace-tech.

<sup>2</sup> Fuhr, Ted, et al. "The Business Case for Medical Device Quality." McKinsey, Oct. 2013, www.mckinsey.com/~media/McKinsey/dotcom/client\_service/Public%20Sector/Regulatory%20excellence/The\_business\_case\_for\_medical\_device\_quality.ashx.

<sup>3</sup> Davis, Jessica. "Data Breaches Will Cost Healthcare \$4B in 2019, Threats Outpace Tech."

<sup>4</sup> "Implantable Medical Devices Market Size, Share, Growth Opportunities and Forecast, 2019–2026." *Acumen Research and Consulting*, 11 Dec. 2019, www.acumenresearchandconsulting.com/implantable-medical-devices-market.

<sup>5</sup> Donovan, Fred. "Organizations See 878% Health Data Growth Rate Since 2016." *HITInfrastructure*, 8 May 2019, hitinfrastructure.com/news/organizations-see-878-health-data-growth-rate-since-2016.