Harnessing Data for Breakthroughs: Electronic Batch Records in Cell and Gene Therapy

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Introduction:

Cell and gene therapies have emerged as groundbreaking approaches for addressing complex diseases. To fully realize their potential, process developers and manufacturers must adopt strategies that enable effective data collection and management. This abstract emphasizes the importance of Electronic Batch Records (EBRs) as a vital tool to facilitate these strategies and unlock the potential of artificial intelligence (AI) in the future.

Discussion:

Providers of starting materials, quality control, and manufacturing play a crucial role in supporting their customers, such as drug development firms, with crucial insights about their products. EBRs enable comprehensive documentation of the numerous steps involved in the cell and gene therapy workflow, including donor qualification, cell isolation, manufacturing, and quality control.

The product procurement and manufacturing lifecycle of cell and gene therapies involve a diverse range of data points, encompassing critical process parameters, quality control measurements, donor or patient-specific information, consumable and excipient details, and equipment parameters. The complexity and data-intensive nature of this comprehensive dataset are vital for ensuring traceability for process control, product quality, and patient safety. The number of data points can vary depending on type of therapy, number of process steps, level of process monitoring, and process complexity. A single batch record from donor qualification through final product release can be upwards of 3,000 specific data points **(Exhibit 1)**.

Exhibit 1: Process Data Points Captured by EBR

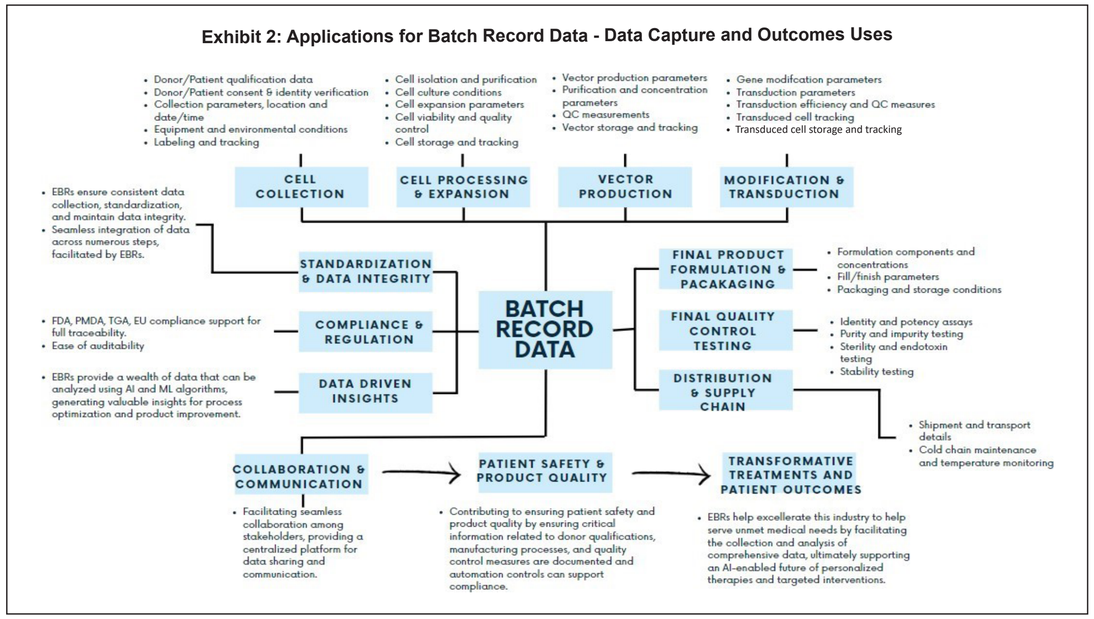
Process	Steps	Data Point Count
Cell Collection	Donor qualification data (age, medical history, genetic screening results, etc.)	100
	Donor consent and identity verification	50
	Cell collection parameters (volume, cell type, collection device details)	100
	Collection location and date/time	50
	Collection equipment and environmental conditions	100
	Donor sample labeling and tracking	100
	Sub-total	**500**
Cell Processing and Expansion	Cell isolation and purification parameters	200
	Cell culture conditions (media components, pH, temperature, etc.)	200
	Cell expansion parameters (passage number, seeding density, growth rate)	200
	Cell viability and quality control measurements	200
	Cell storage and tracking	200
	Sub-total	**1000**
Gene Therapy Vector Production	Vector production parameters (plasmid details, transfection method, viral titer)	200
	Vector purification and concentration parameters	200
	Vector quality control measurements	200
	Vector storage and tracking: 200 data points	200
	Sub-total	**800**
Gene Modification and Transduction	Gene modification parameters (editing tool, editing efficiency)	200
	Transduction parameters (vector-to-cell ratio, transduction method)	100
	Transduction efficiency and quality control measurements	100
	Transduced cell storage and tracking	100
	Sub-total	**500**
Final Product Formulation and Packaging	Formulation components and concentrations	100
	Fill/finish parameters (vial size, labeling, sealing)	50
	Packaging and storage conditions	50
	Sub-total	**200**
Final Quality Control Testing	Identity and potency assays	200
	Purity and impurity testing	100
	Sterility and endotoxin testing	100
	Stability testing	100
	Sub-total	**500**
Distribution and Supply Chain	Shipment and transport details	50
	Cold chain maintenance and temperature monitoring	50
	Sub-total	**100**
	TOTAL	**3600**

The FDA recognizes the significance of data in advancing these therapies and has provided guidance on its utilization, emphasizing the importance of robust data collection, analysis, and process control throughout the manufacturing process and publishing a framework for the regulatory considerations for AI and machine learning (ML) algorithms in medical devices. EBRs can help facilitate meeting these guidelines and frameworks.

Conclusion:

EBRs play a pivotal role in enabling comprehensive data collection, standardization, and integrity and can harness the range of data points involved in the product procurement and manufacturing lifecycle to improve compliance, leverage data-driven insights and unlock the full potential of AI. All of which support the advancement of transformative treatments, improving patient outcomes and addressing unmet medical needs **(Exhibit 2)**.

Exhibit 2: Applications for Batch Record Data - Data Capture and Outcomes Uses



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U.S. Food and Drug Administration. (2019). Framework for Regulatory Oversight of Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD).