

# GE Healthcare

## Transforming the Human Drug Application Process Through Effective Use of Information Technology

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# Topics

Role of Electronic Health Records (EHR)

Role of EHR Data Aggregation

Leveraging National Interoperability Initiatives

Expanding use of IT in Personalized Medicine

Creating an FDA Roadmap... Focused on Processes



# Role of Electronic Health Records

Comprehensive, longitudinal patient record

Efforts to harmonize standards, vocabularies & data

Increased focus on EHR adoption

Broadening physician participation

Ensuring solutions that do not compromise workflow

# Role of EHR Data Aggregation

Aggregation of EHR data for secondary use

Outcome study analysis

Identification of drug trial candidates

Pharmacosurveillance

Synergies with future quality reporting aggregation

# Leveraging National Interoperability Initiatives

Standards harmonization

National interoperability momentum

Industry collaboration to create interoperability standards

# Expanding use of IT in Personalized Medicine

Early Health model: predict, diagnose, treat, monitor, inform

Target diseases through specific diagnostics & therapies

Accuracy of identifying right candidates for clinical trials

Reduced costs enable niche therapies to be considered

Performed in an environment that respects privacy

# Creating an FDA Roadmap... Focused on Processes

EHRVA Roadmap provides a model for FDA to benchmark

Involving all stakeholders

Harmonize processes & standards w/ other agencies

Create pragmatic, incremental milestones

Flexibility for stakeholders to test new processes



# Summary

IT can enable process transformation across all phases

Interoperable solutions balance data collection rigor w/ sensitivity to physician workflow

Leverage momentum driven by EHR adoption and creation of Nationwide Interoperable Infrastructure

Transformation roadmap created by all stakeholders, with measurable & achievable incremental milestones



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