The Role of EHRs in Increasing the Safe and Effective Use of Biosimilars

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Agenda

- Biologics and Biosimilars: An Overview
- Legislative and Regulatory Activity
  - Biosimilar Naming
  - Pharmacy Substitution
- Impact of Biosimilars on HIT Vendors
- Summary and Conclusion

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Biologics and Biosimilars: An Overview

Biologics and Biosimilars

News about Biologics and Biosimilars is everywhere

THE WALL STREET JOURNAL.

On the Horizon

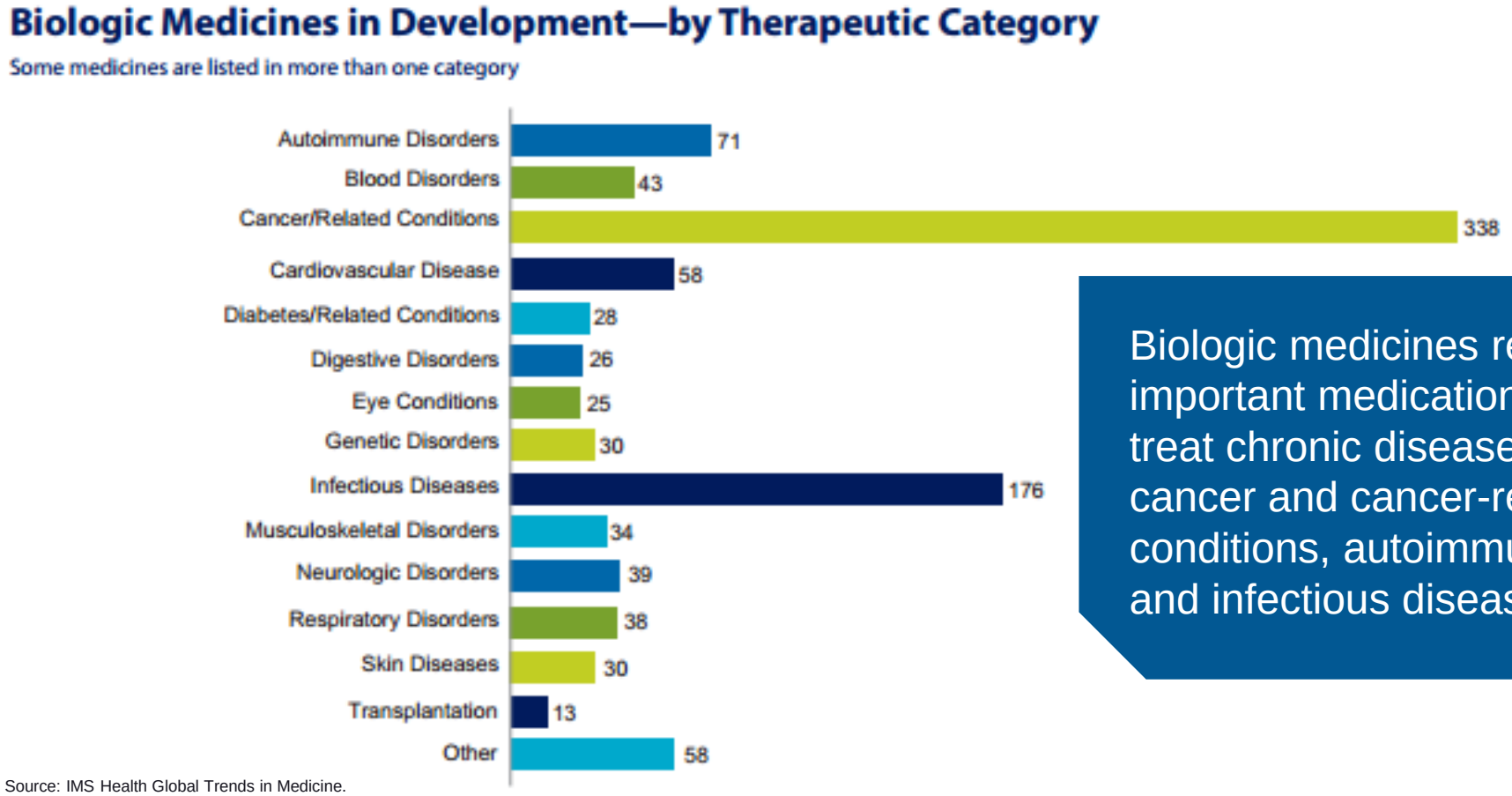
Lower-priced competition is coming to the U.S. for some expensive biotech drugs, as big companies develop their own 'biosimilar' versions.

DRUG	Humira	Enbrel	Remicade	Lantus	Neulast
2014 U.S. SALES	$7.22 billion	$5.51	$4.50	$4.47	$3.83
COMPANY	AbbVie	Amgen	J&J	Sanofi	Amgen
TREATS	Rheumatoid arthritis	Rheumatoid arthritis	Rheumatoid arthritis	Diabetes	Infectic during chemo
RIVALS DEVELOPING BIOSIMILARS	Amgen, Boehringer Ingelheim, Novartis, Pfizer, Samsung	Baxter, Novartis, Samsung	Hospira, Pfizer, Samsung	Eli Lilly, Merck & Co./ Samsung, Mylan	Apote Nova Hosp Mer My

Source: Bernstein Research *Received FDA approval in March 2015

Why Are Biologics so Important?

Biologics hold great promise for providing a lower cost treatment option for chronic diseases



Source: IMS Health Global Trends in Medicine.

Biologic medicines represent many important medications used to treat chronic diseases including cancer and cancer-related conditions, autoimmune disorders, and infectious diseases.

What Makes Biologics Different?

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Biologic: Worldwide, a practical definition of a biologic is a product of which the **active ingredient is made in a living system**

Biosimilar: A **biologic product** that is approved based on a showing that is highly similar to an already approved biologic product, and **has no clinically meaningful differences** in terms of safety from the reference product

Interchangeable Biologic: An FDA designation stating that switching patients between such products can be made by a pharmacist

Conventional Medications: Typically manufactured through **chemical synthesis** (made by combining specific **chemical ingredients** in an ordered process) and have well-defined chemical structures

Biosimilars: They're Not Your Grandma's Generics

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Biosimilars can not be treated the same as generics

BIOSIMILARS vs GENERICS:

Generic versions of chemically synthesized drugs contain the same active ingredient and are considered therapeutically equivalent.

Biosimilars may not contain identically active substances to their biologic reference product.

Two Biosimilars Categories

Biosimilar – Requires analytical studies to show product is "highly similar"

Interchangeable Biosimilar – Requires biosimilarity AND the determination that switching between the reference product and the biosimilar does not impact safety or efficacy

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Legislative and Regulatory Activity Around Biosimilars

Biosimilars: Legislative and Regulatory Activity

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It's all about patient safety

- **Biosimilar Naming**
  - FDA released draft guidance and rule on Nonproprietary biologic product naming (August 2015)
- **Biosimilar Substitutions and Interchangeability**
  - Legislation in 22 states
  - FDA Draft Guidance expected in 2016
- **Biosimilar tracking and reporting for adverse drug events (ADEs)**

FDA Draft Guidance & Rule on Biosimilar Naming

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FDA proposes:

- An FDA-designated suffix be added to the nonproprietary biologic name
  - Suffix would be composed of a random set of 4 lowercase letters
- Changing the names of 6 existing reference and biosimilar products
  - Add suffix to the nonproprietary name

Example:
Nonproprietary name of reference product:
replicamab-cznm

Biosimilar of that product:
replicamab-hixf

Guidance seeks to address 2 main issues: Help prevent inadvertent substitution and provide support for after-market safety monitoring of all biologic products.

Biosimilar Substitution

A flurry of state-level activities

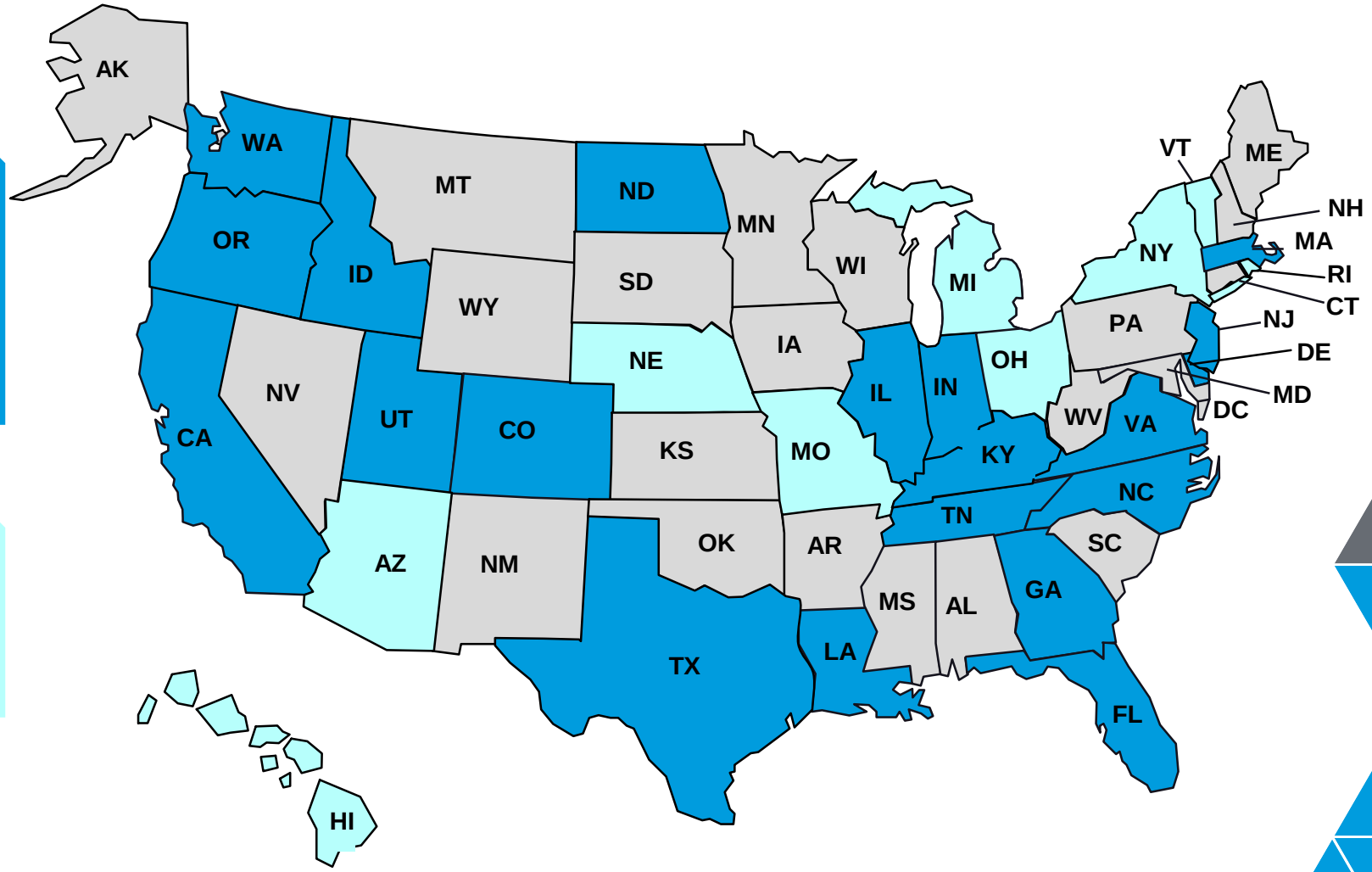
- New laws/regulations are emerging around biosimilar substitutions and physician notification
  - Amending current statutes and pharmacy board generic substitution rules to accommodate biosimilars
- 28 states are considering or have passed legislation establishing standards for substitution of a biosimilar product

FDA Draft Guidance around biosimilar substitution expected in 2016

Pharmacies Are Required to Notify the Prescriber for Biosimilar Substitution

22 States with Current Rules:
Notification timeline varies from 24 hours (ND) to 5 days (CA)

9 States + Puerto Rico with Pending Legislation



Source: National Conference of State Legislatures, State Laws and Regulations related to Biologic Medications and substitution of biosimilars, April 2016

Tracking of Biosimilar ADEs

Why is it important?

- **Dispensing Location**
  - Traditional medications are primarily dispensed directly from pharmacist to patient
  - Dispensed product identification is a greater challenge when dispensing and administration are in different settings
- **Biosimilar Substitution**
  - Delayed immunologic reactions may make it difficult to attribute the event to a specific product
- **Patient Safety and Confidence**
  - Achieve early identification of batch or product-specific problems
  - Build consumer confidence around these new types of medications

Biosimilar tracking for ADEs

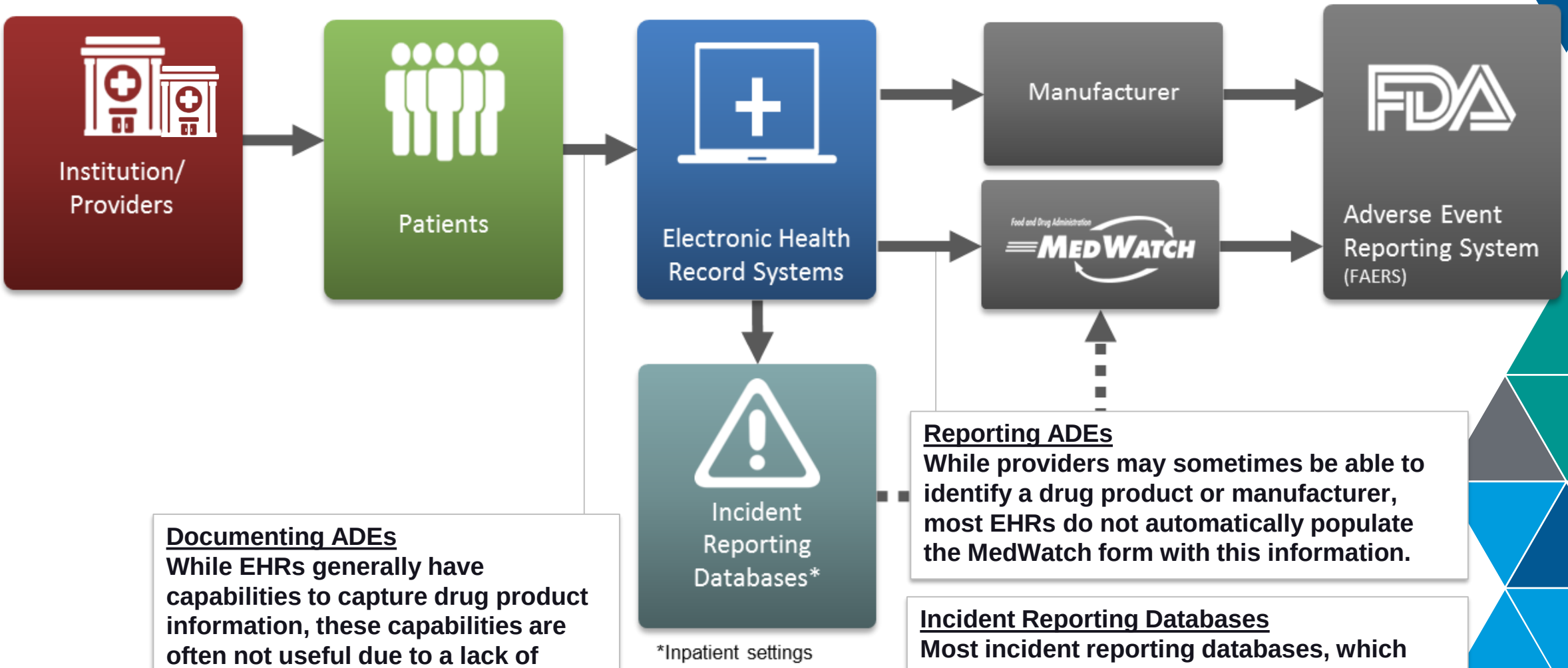
Two current ADE tracking systems

Passive surveillance system: Relies on proactive reporting by physicians and pharmacies

Active surveillance system: Relies on retrospective analysis of medical records at Sentinel-affiliated sites and drug or disease registries

Existing ADE monitoring infrastructure lacks capability for tracking biologics/biosimilars in existing drug data tables

Tracking of ADEs



Documenting ADEs
While EHRs generally have capabilities to capture drug product information, these capabilities are often not useful due to a lack of specific manufacturer identifiers.

Reporting ADEs
While providers may sometimes be able to identify a drug product or manufacturer, most EHRs do not automatically populate the MedWatch form with this information.

Incident Reporting Databases
Most incident reporting databases, which are often used to internally track adverse events within hospitals, are NOT able to automatically populate the MedWatch form.

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Impact of Biologics on Health Care Information Technology (HIT) Vendors

Biosimilar Naming: Impact on HIT Vendors

How will Biosimilar Naming impact your product?

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EHR Vendors

- Understand how compendia will handle biosimilar naming
  - Plan for any required changes to accommodate suffix
- Validate if drug search functions and displays need to be modified to accommodate longer drug names
- Determine if electronic health record (EHR) formulary and drug selection displays need to be modified for biosimilar products covered under a formulary benefit
- Ensure timely compendia file update process
- Evaluate impact of potential name change of existing product on medication history, patient records, etc

Biosimilar Naming: Impact on HIT Vendors

How will Biosimilar Naming impact your product?

Pharmacy Vendors

- Ensure system is updated on a timely basis with new compendia file
- Review refill requests to ensure correct biosimilar is being dispensed
- Prepare to provide manufacturer and lot number information in RxFill and medication history data

Biosimilar Substitution: Impact on HIT Vendors

Impact of legislation around physician notification of biosimilar substitution and ADE tracking

EHR and Pharmacy System Vendors

- Stay abreast of legal and regulatory requirements for communication with physician on any substitution of a biosimilar
  - Incorporate functionality into the EHR to support such notification from pharmacies to physicians
- NCPDP SCRIPT Medication History and RxFill transactions can include the NDC, manufacturer, and lot number as part of the notification to the prescriber
  - **Prepare for adoption of RxFill**

National Council for Prescription Drug Programs (NCPDP) is the standards development organization which maintains SCRIPT.

SCRIPT is a electronic data interchange (EDI) standard used for ePrescribing

Tracking of Biosimilars for ADE Reporting: Impact on HIT Vendors

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EHR Vendors

Currently, there is no way to distinguish in the EHR between the product ordered and what was dispensed. To accommodate receipt in the EHR of manufacturer and lot number information for biosimilars from pharmacies, enhancements will be needed:

- Add fields to record the NDC code, manufacturer, and lot number of biologics and biosimilars which have been dispensed
- Add fields to record NDC, manufacturer, and lot number in the medication administration workflow. GS1 codes and barcoding may provide a quick and effective method to enter these data
- Add new workflow and data fields to be populated by the RxFill data supplied by the pharmacy

Summary and Conclusion

- Biosimilars are here and many more are coming to market
- Biosimilar pharmacy substitution is different than generic substitution and is based on an FDA interchangeability designation
- State laws require pharmacists to communicate with a prescriber following a substitution
- Point-of-care tracking of biologic/biosimilar ADEs is essential
- EHRs, e-Prescribing, and Pharmacy Information Systems must adapt to accommodate:
  - Biosimilar drug names
  - Receipt of substitution communication
  - Receipt of expanded drug information from pharmacies on MedHx and RxFill
  - Tracking and reporting of biologic/biosimilar ADEs at the point of care

Prescribing and dispensing of biosimilars is a new dimension for physicians and pharmacies. Adaptation of existing technologies to accommodate the unique characteristics of biosimilars will ensure access and patient safety.

Thank You

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Tracking of ADEs

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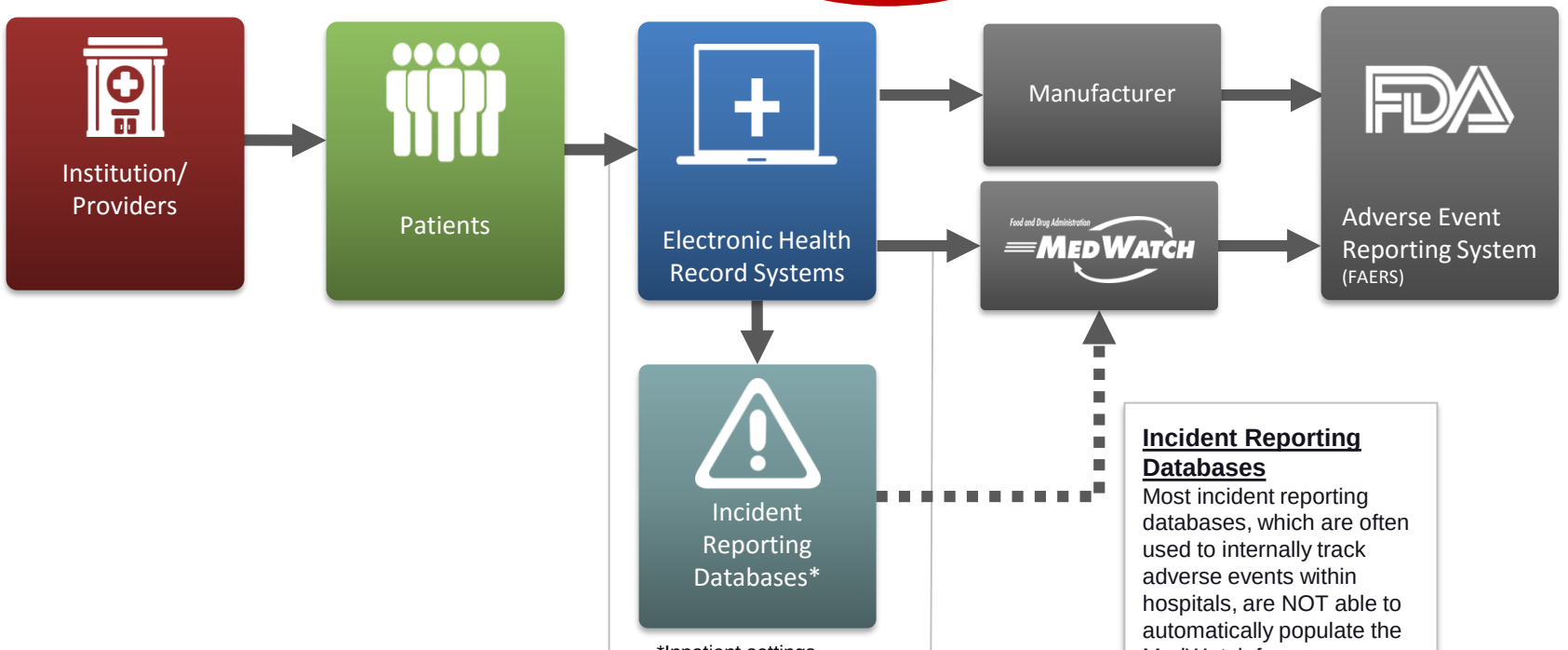

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