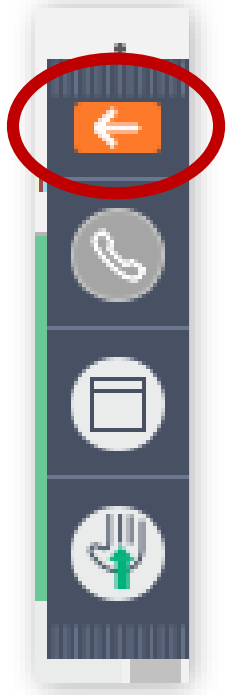
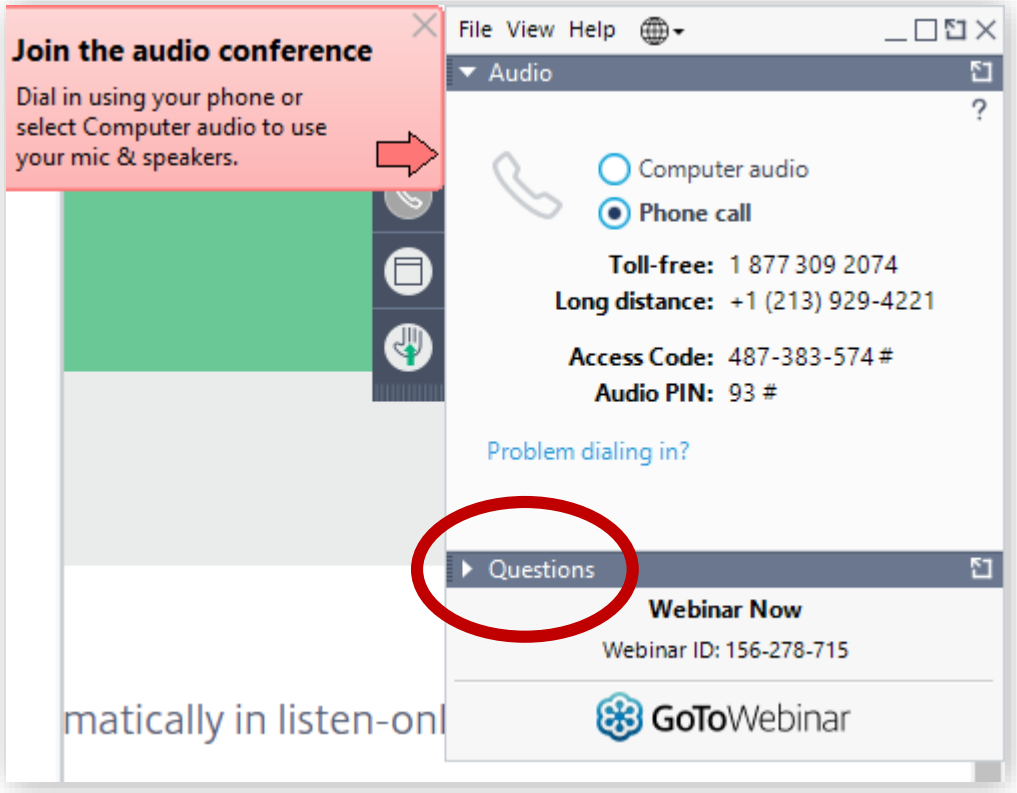
Health Technology Challenges and Opportunities Launching a Biosimilar

What Every Marketer Needs to Know

Point-of-Care PARTNERS
HEALTH IT MANAGEMENT CONSULTANTS

GoToWebinar Logistics





Answer in Question Panel:
What is your biggest health IT challenge launching new drugs today?

Speaker Introductions

Pooja Babbrah

Point-of-Care Partners Practice Lead, PBM Services

NCPDP Biologic and Biosimilar Access and Traceability Task Group Leader

Craig Kemp

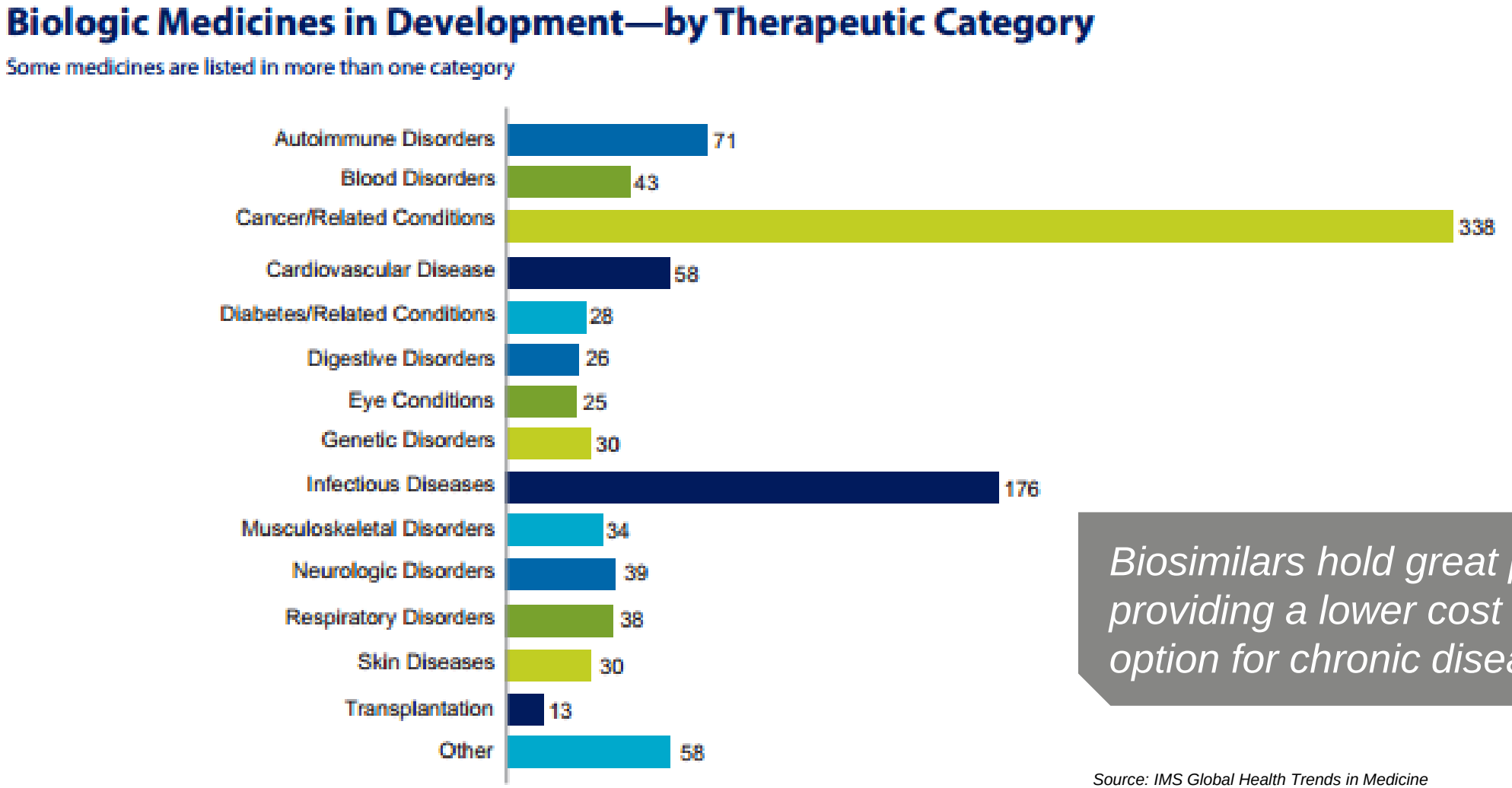
Point-of-Care Partners Senior Consultant, Life Sciences

Agenda

- The Impact of Biologics in Todays Healthcare Environment
- The Biosimilar Market
  - How do Biosimilars differ from Biologics
  - Regulatory activities affecting ePrescribing of Biologics and Biosimilars
- Ordering and Prescribing Biosimilars in the EHR
- EHR Considerations for Brand Launch Plan

The Impact of Biologics in Today's Healthcare Environment

Why Are Biologics so Important?

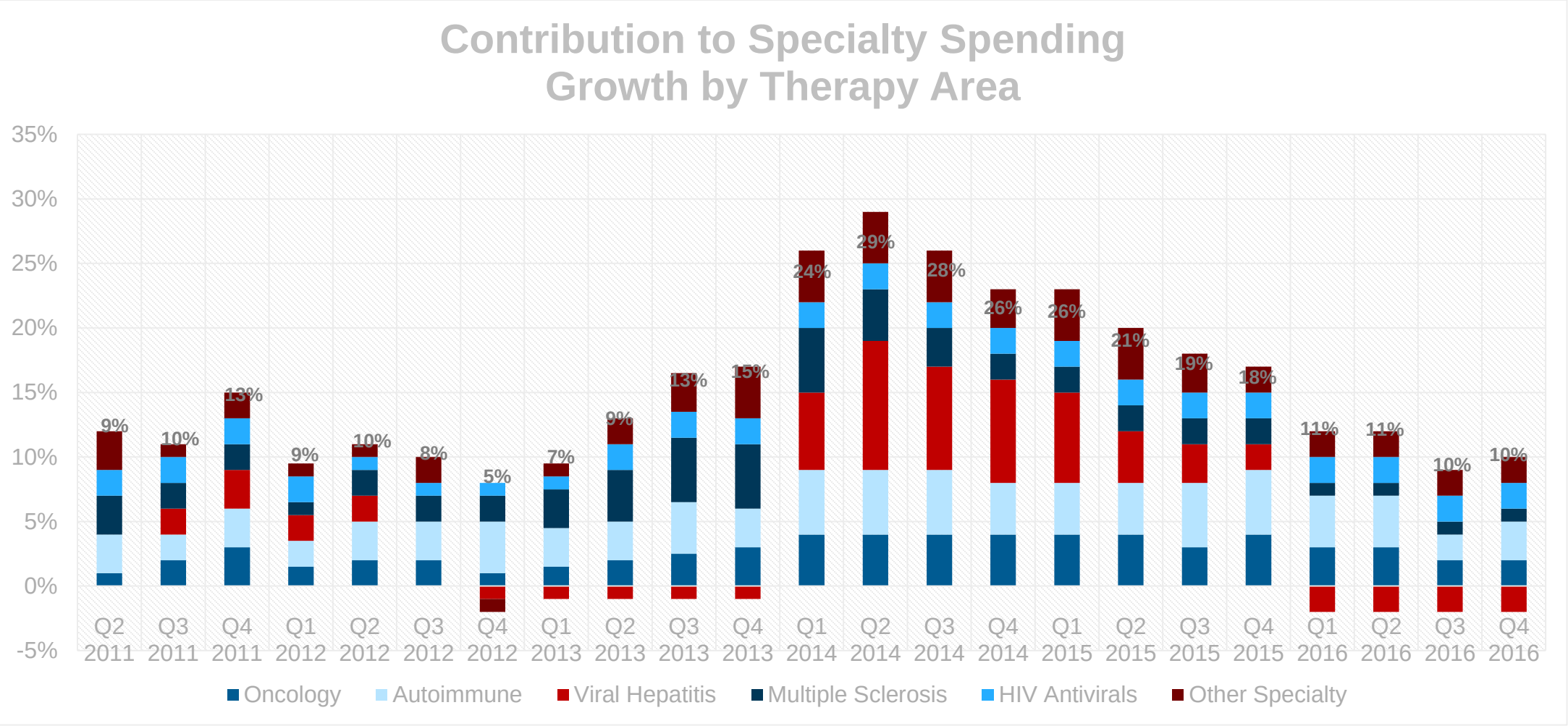


Biosimilars hold great promise for providing a lower cost treatment option for chronic diseases

Source: IMS Global Health Trends in Medicine

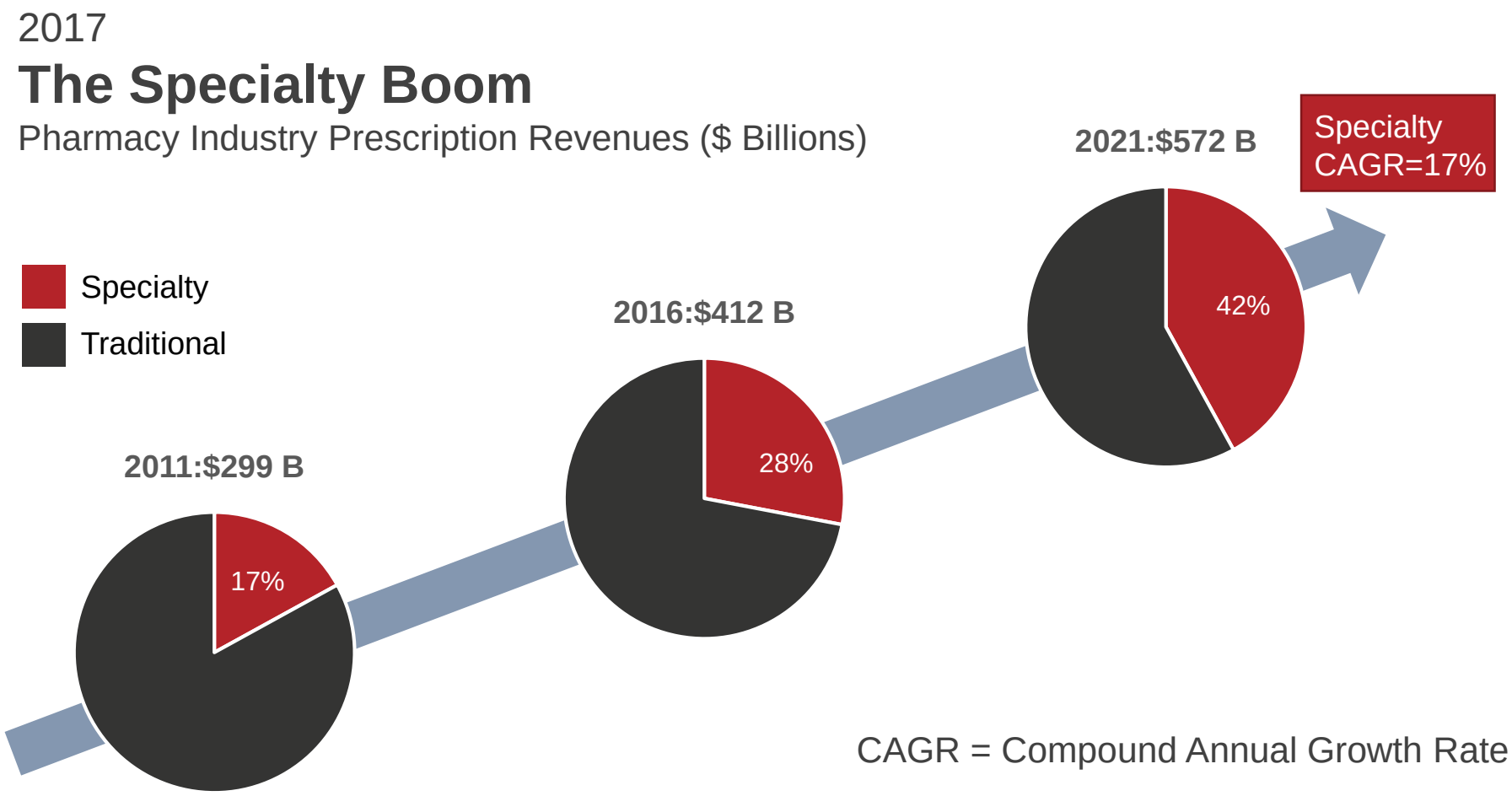
Growth of Pharmacy Specialty Spend

On average, specialty spending has been increasing at approximately 10% per year



Source: QuintilesIMS, National Sales Perspectives, Dec 2016

The Biologic Market is an Increasing Amount of the Total US Drug Spend



Source: The 2017 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers, Exhibit 66. Includes prescription revenues from retail, mail, long-term care, and specialty pharmacies.

The Biosimilar Market

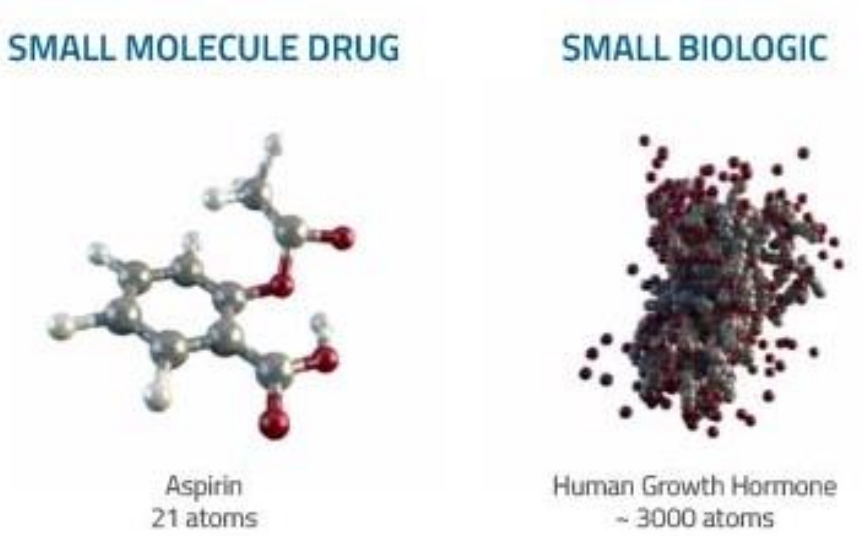
Biologics: What are they?

Biologics

- Very large, complex molecules or mixtures of molecules
- Manufactured in a living system such as a microorganism, or plant or animal cells; often produced using recombinant DNA technology
- Difficult, and sometimes impossible, to characterize a complex biologic by testing methods available in the laboratory, and some of the components of a finished biologic may be unknown

In contrast to most drugs that are chemically synthesized with known structures, most biologics are complex mixtures that are not easily identified or characterized.

Source: Hospira: About Biologics; Presented at FDB Care Guidance Conference, 2016



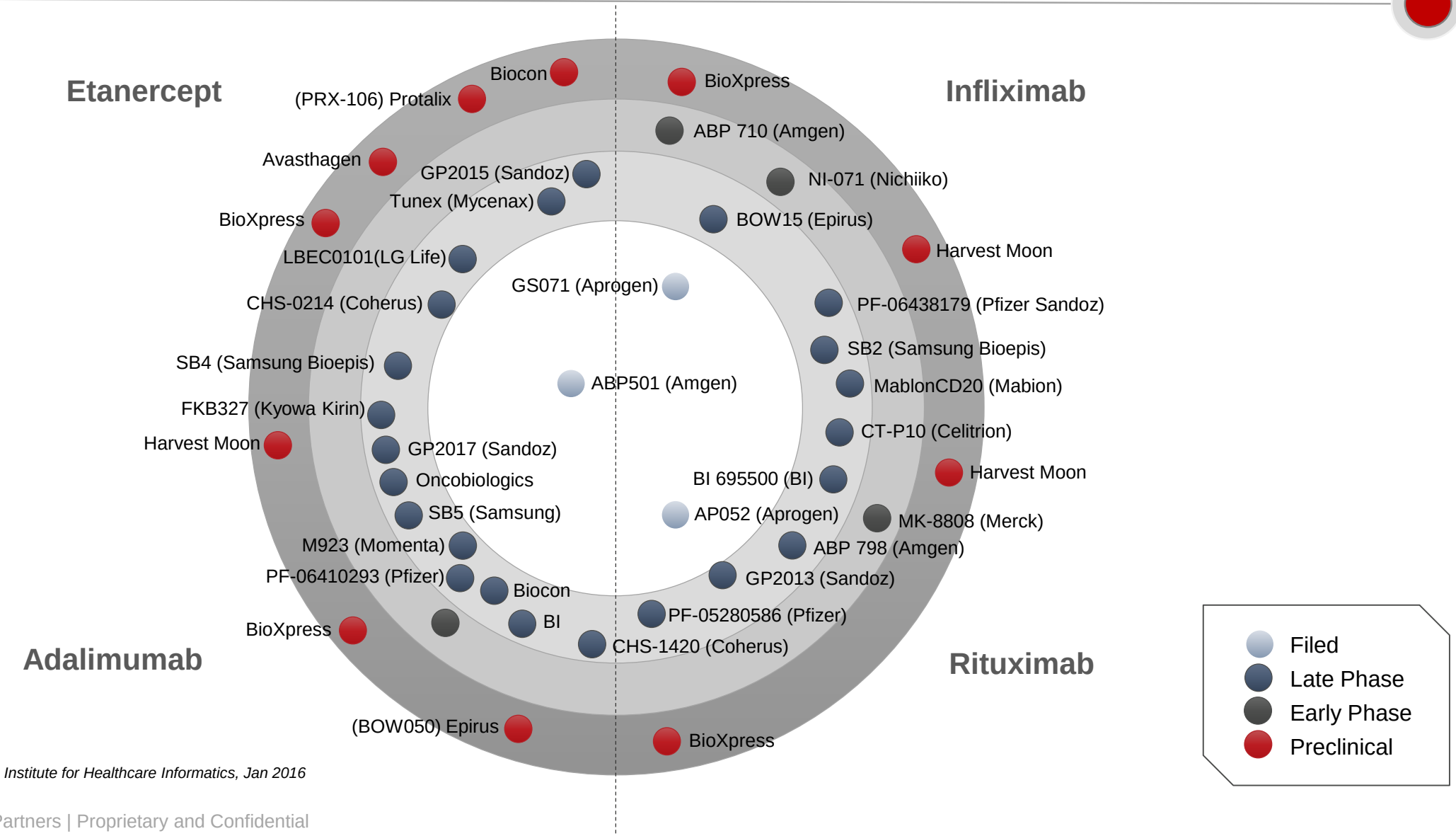
Conventional Medications

- Typically manufactured through chemical synthesis (made by combining specific chemical ingredients in an ordered process)
- Have well-defined chemical structures
- Finished drug can usually be analyzed in a laboratory to determine all its various components

Biosimilars: What are they?

	Generic Molecules	Biosimilars
Definition*	Generic **equivalent.** A drug that is no longer under patent protection, which may be produced by any manufacturer who follows good manufacturing protocols. **Identical to the innovative original drug**	A **biopharmaceutical** which is produced by a **different manufacturer after** the **expiration of the patent** and marketing exclusivity of an original innovative biological product (e.g., a therapeutic monoclonal antibody). **Highly similar to original biologic.**
Rules on Substitution	**Interchangeable** and therefore **substitutable** without prescription in all states (considered **therapeutically equivalent**) – Hatch-Waxman Act (1984)	**Not** always **therapeutically equivalent** and **interchangeable** (different active ingredient) 1. **Biosimilars:** analytical studies show product is "**highly similar**" 2. **Interchangeable Biosimilar:** Requires **biosimilarity AND** switching from original biologic **does not impact safety or efficacy**

A Wave of Biosimilars are Launching Over the Next Several Years



Source: IMS Health, IMS Institute for Healthcare Informatics, Jan 2016

Regulatory activities affecting ePrescribing of Biologics and Biosimilars

Biologic and Biosimilar Naming	• FDA final guidance on Non-Proprietary biologic product naming released January 2017 • Adds a 4-digit random suffix to end of name • Requires name change for existing products on the market
Biologic and Biosimilar Substitution Communication	• Legislation in 32 states • Notification of substitution must be sent to provider • NCPDP eRx standards organization added category to RxFill standard to allow for electronic communication of substitution information
Biosimilar Interchangeability	• FDA Draft Guidance released January 2017 • Outlines what is required to demonstrate interchangeability of biosimilar including switching studies and presentation of the product (container closure system, delivery device, etc.)

FDA Final Rule on Biologic Naming: Jan, 2017

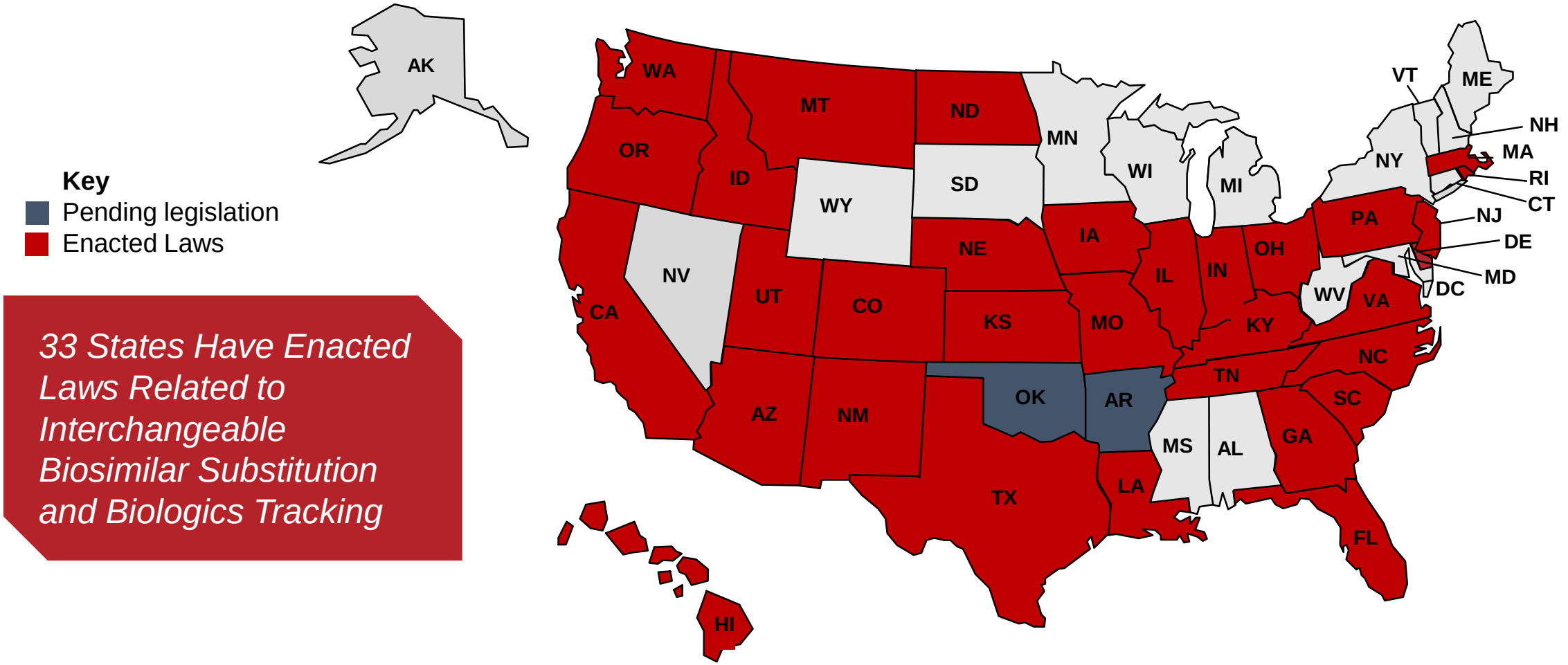
- An FDA-designated suffix be added to the nonproprietary biologic name
  - Suffix is composed of a random set of 4 lowercase letters
- Name change of existing reference and biosimilar products
  - Add suffix to the nonproprietary name

Example:
Nonproprietary name of reference product:
replicamab-cznm

Biosimilar of that product:
replicamab-hixf

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

Biologic and Biosimilar Substitution Notification



33 States Have Enacted Laws Related to Interchangeable Biosimilar Substitution and Biologics Tracking

Source: ePrescribing State Law Review by Point-of-Care Partners June 14, 2017

Biologics and Biosimilars Substitution Communication: Key Provisions of Legislation and Standards Update

1. FDA Certified Interchangeability
2. Patient Notification
3. Prescriber's "Brand Medically Necessary" Blocks Substitution
4. Pharmacy Records Must Be Retained
5. Posted List of Interchangeables
6. Price related provisions
7. Other provisions
    1. Liability Protection
    2. Timeframe for communication

- NCPDP Biologics and Biosimilars Task Group Formed Sept, 2016
- **Goal:** Evaluate existing NCPDP standards on viability for use as electronic communications from pharmacy to provider for biologic and biosimilar substitution
- **DERF passed at NCPDP meeting, May 2017**
- Will allow electronic communication of biologic and biosimilar substitution using RxFill

Interchangeability: FDA Draft Guidance

Interchangeability Draft Guidance: In Comment Period

Guidance on required testing and proof of interchangeability including switching studies and post-marketing data

- Biosimilarity requirements are met first
- Totality of evidence will be considered
- Data and information showing product can be expected to produce the same clinical result as the RP* in ALL of the RP's licensed conditions of use expected
- Seeking licensure for ALL RP's licensed conditions of use recommended
- Extrapolation is acceptable when justified
- Switching studies generally expected
- Presentation/s generally limited to those of the RP
- Post marketing safety monitoring may be required but is itself not sufficient

* RP = Reference Product

Biosimilar tracking for Adverse Drug Events

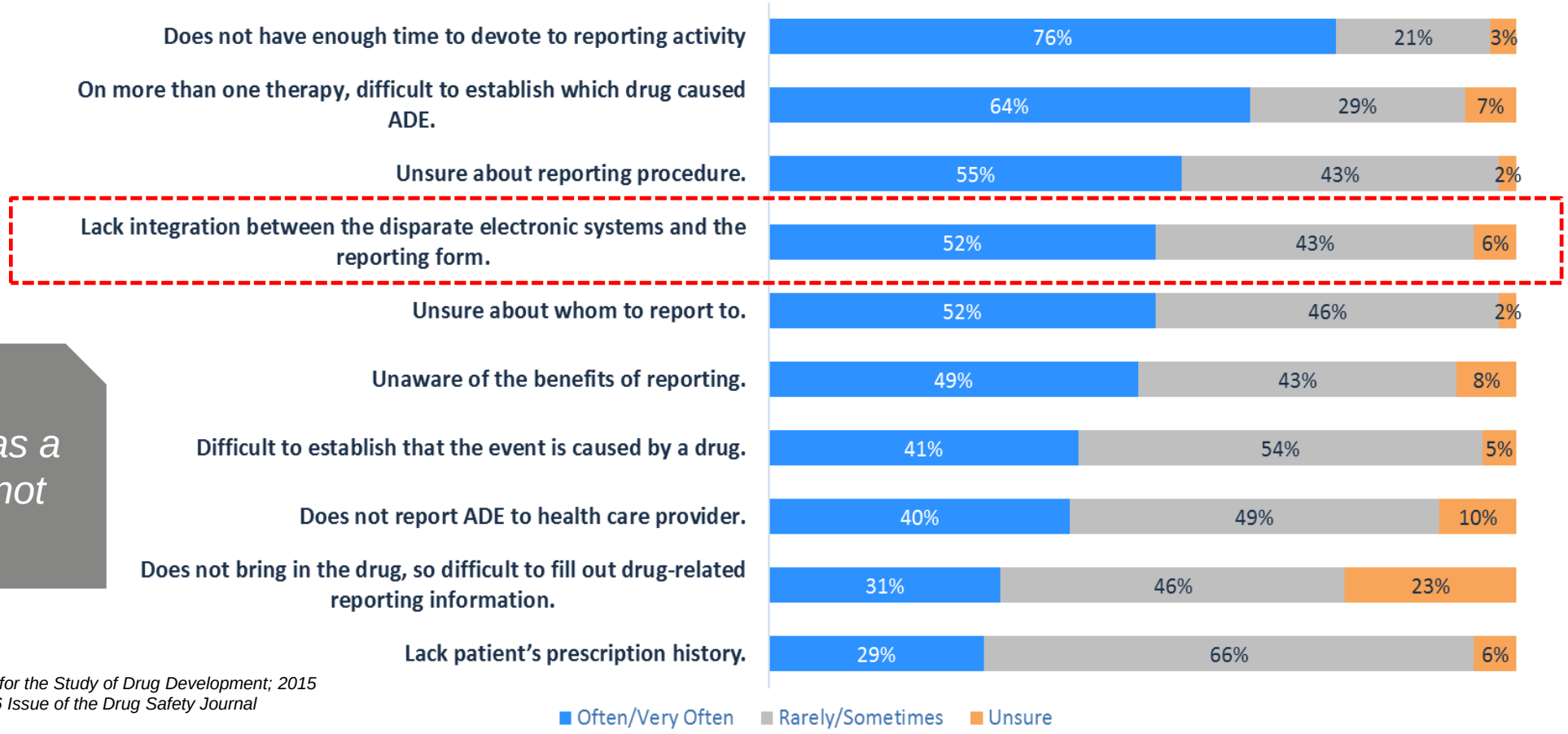
Passive surveillance system: Relies on proactive reporting by physicians and pharmacies

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

Currently, there is no pending legislation or FDA guidance around tracking and reporting of ADEs, yet given the complex nature of biosimilars the ability to trace an ADE back to the originating product will be an important safety monitoring process

Research on Reason for not reporting ADEs

Question posed to Hospital Practitioners including MDs, Pharmacists and Nurses:
"Based on your experience, how often do each of these reasons prevent health care providers from reporting ADEs to the FDA or the manufacturer?" **(n = 87)**



Lack of system integration was cited as a significant reason for not reporting ADEs (52%)

Source: Results of study conducted by Tufts Center for the Study of Drug Development; 2015 and 2016.Recently published in the November, 2016 Issue of the Drug Safety Journal

Summary

- The Biologics market will continue to grow over the next several years
  - Numerous Biologics in development including Biosimilars
- Biosimilars offer great opportunity to increase access to medications and lower costs
- However, the complex nature of Biosimilars make substitution more complex than Generic medications
- Regulatory activities such as naming, substitution and adverse experience reporting are complex and still in development
- EHRs and ePrescribing technologies will need to adapt to make Biosimilars accessible and easy to prescribe

Ordering and Prescribing Biosimilars in the EHR

The EHR market continues to expand as most HCPs have integrated the technology into their practices

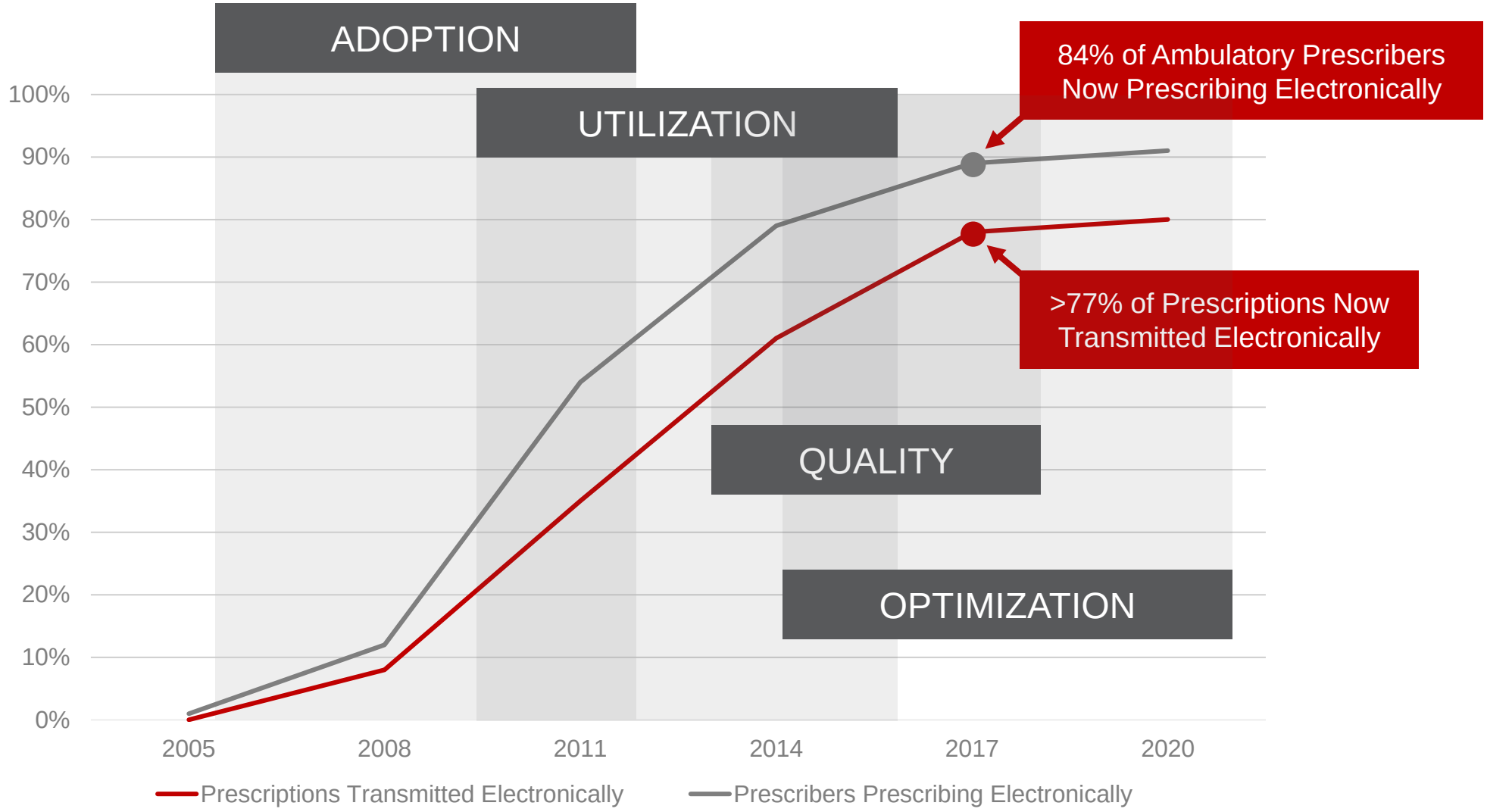
EHR systems are becoming the digital platforms where doctors practice: **>85% of physicians are ePrescribing** and **>80% of office-based physicians are using EHRs**

HCPs spend an average of **3.3 hours per day using EHR systems**, twice as long as on all other digital resources combined

Opportunities exist to integrate utilization management tools within EHRs and ePrescribing workflow for **both specialty and non-specialty medications**

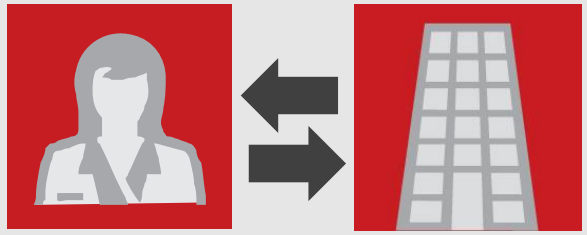
References: CMI Media; Decision Resource Group; GHG

The Evolution of ePrescribing



There are multiple prescription transactions required to prescribe and administer a biosimilar

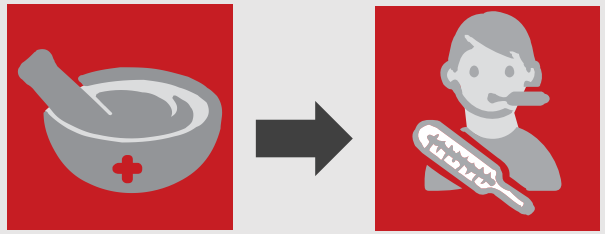
Prescribe



Prescriber Payer

Via:

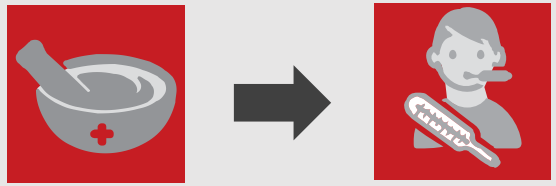
Dispense



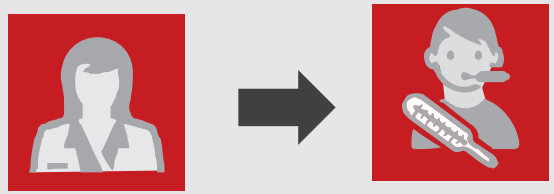
Pharmacy Patient

Via:

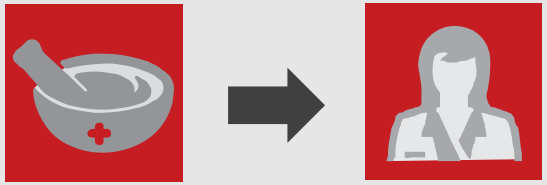
Care Coordination



Pharmacy Patient



Prescriber Patient



Pharmacy Prescriber

Via:

EHR technology is continually evolving to meet the information needs of HCPs and patients

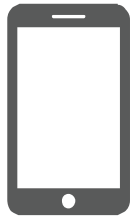
PHYSICIAN PRACTICE
EMR or e-Rx System

A
Eligibility
B

Real-Time
Pharmacy Benefit
Prior Authorization

PBM or PLAN
Claims Processing System Benefit
Plan Rules, Formulary, History

Adherence &
Counseling

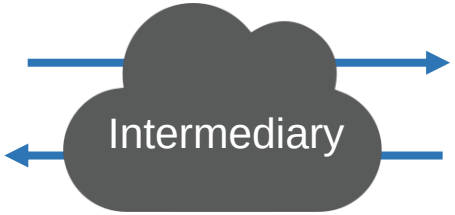


Patients

Pharmaceutical
Manufacturers

REMS

“Clean” ePrescription
(w/addl information)



Intermediary

PHARMACY
Pharmacy Dispensing System

Financial Assistance
for Copays

Foundations

EHRs now run the clinical workflow and the industry is rapidly evolving to meet the needs of HCPs

- Almost all HCPs who will prescribe Biosimilars are using EHRs to prescribe and administer specialty medications
- Multiple intermediaries and drug information databases collaborate to provide the necessary information and transactions
- The EHR and health technology market will evolve over the next several years to meet the needs of HCPs and patients

Understanding EHRs is critical to understanding the market and customer needs

EHR Considerations for a Biosimilar Launch

Every step in the biosimilar buying process flows through EHRs and health IT

- HCPs will only prescribe a biosimilar they can easily identify, prescribe and administer in their EHR
- A through understanding of the EHR clinical workflow and how it impacts the prescribing of a biosimilar is a critical to a successful launch

Steps in the Buying Process	*Selected EHR and Health IT Function*
Origination	• Population Health • Patient Lists • Patient Outreach
Evaluation Diagnosis	• Clinical Alerts • Clinical Decision Support
Treatment Choice	• Clinical Quality Measures (eCQMs) • Order Sets
Brand Choice	• ePrescribing • Formulary Indicators • Favorites
Prescription Fulfillment	• ePrior authorization • Prescription Drug Monitoring Programs
Compliance Adherence	Clinical Summaries Patient Portals Electronic Patient Education

Four customer needs must be met for a successful Biosimilar launch

- **HCPs need to easily prescribe, order and administer a biosimilar in the EHR clinical workflow**

1. Access in EHR

HCPs need to easily identify and prescribe a biosimilar in the EHR

2. Prescribing

HCPs need to understanding how to correctly prescribe a biosimilar

3. Patient Information

HCPs need MCO formularies and prior authorization requirements

4. Patient Engagement

HCPs need to engage and educate patients for successful treatment

Naming convention requires understanding how a biosimilar will appear in EHRs

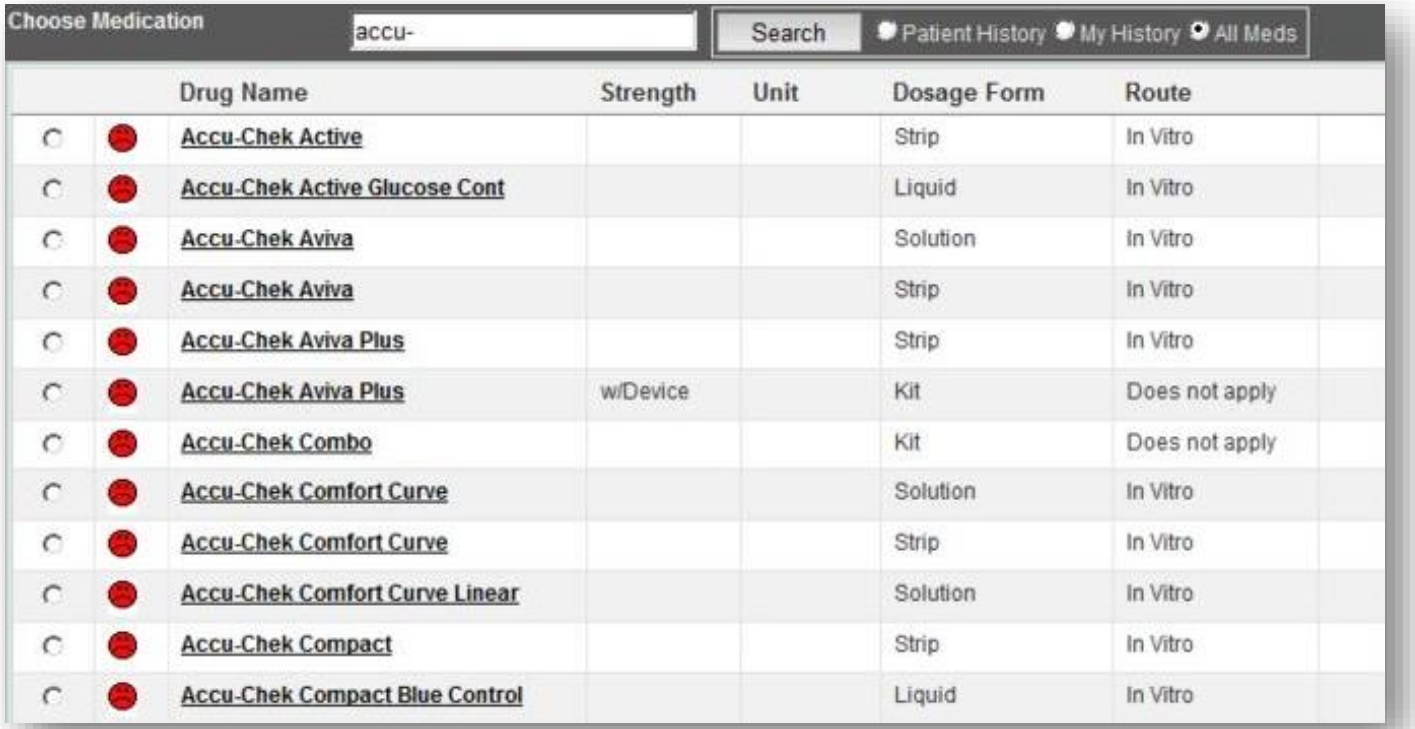
1. Access in EHR
HCPs need to easily identify and prescribe a biosimilar in the EHR

Biosimilar must be available in EHRs to be prescribed

Product Naming should consider how product will be listed in ePrescribing systems

- All EHRs license a drug list from a Compendia Publisher
- HCPs will need to be able to identify a biosimilar and easily distinguish it from the reference biologic

Validating the Compendia have correctly listed a biosimilar and that it is easily identifiable to HCPs is critical to successful launch



Drug Name	Strength	Unit	Dosage Form	Route
Accu-Chek Active			Strip	In Vitro
Accu-Chek Active Glucose Cont			Liquid	In Vitro
Accu-Chek Aviva			Solution	In Vitro
Accu-Chek Aviva			Strip	In Vitro
Accu-Chek Aviva Plus			Strip	In Vitro
Accu-Chek Aviva Plus	w/Device		Kit	Does not apply
Accu-Chek Combo			Kit	Does not apply
Accu-Chek Comfort Curve			Solution	In Vitro
Accu-Chek Comfort Curve			Strip	In Vitro
Accu-Chek Comfort Curve Linear			Solution	In Vitro
Accu-Chek Compact			Strip	In Vitro
Accu-Chek Compact Blue Control			Liquid	In Vitro

The EHR clinical workflow depends on a biosimilar's site of administration, formulation and package configuration

2. Prescribing
HCPs need to understanding how to correctly prescribe a biosimilar

Biosimilars administered by an HCP are ordered differently than a self-injected biosimilar

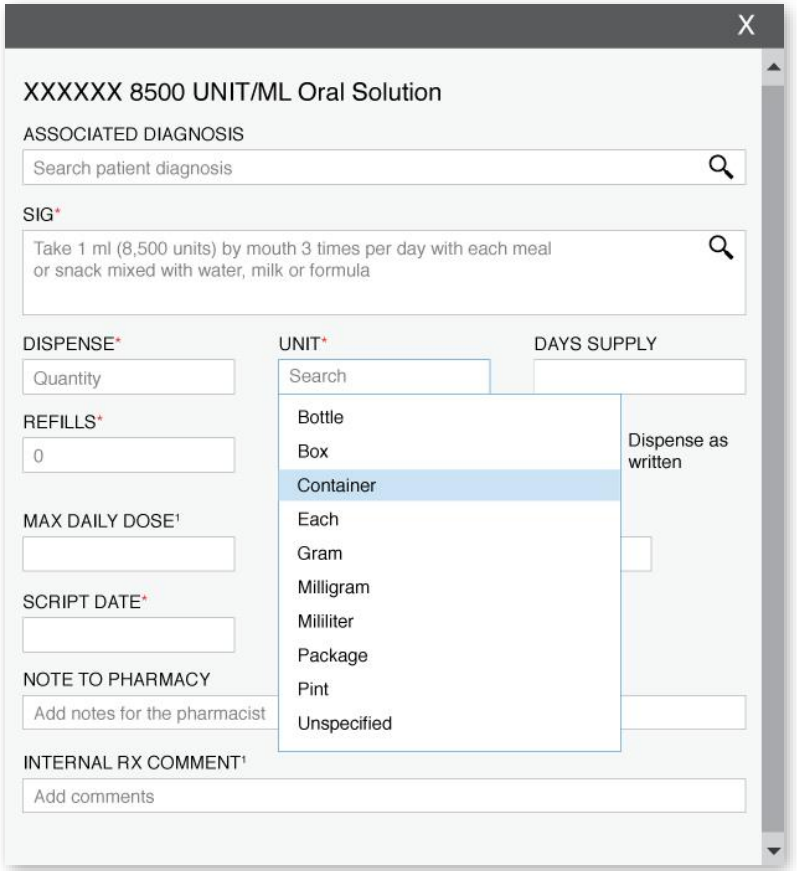
HCP administered biosimilars are covered in the patient's medical benefit and have different payment policies

Liquid formulations are more difficult to order

- Quantity selection options aren't obvious
- Conversion by prescriber may be necessary

It's important HCPs understand how to correctly prescribe a biosimilar

- Confusion can result in decreased conversion from the more familiar reference biologic



Biosimilars will be subject to MCO cost controls such as formularies, step edits and prior authorizations

3. Patient Information

HCPs need MCO formularies and prior authorization requirements

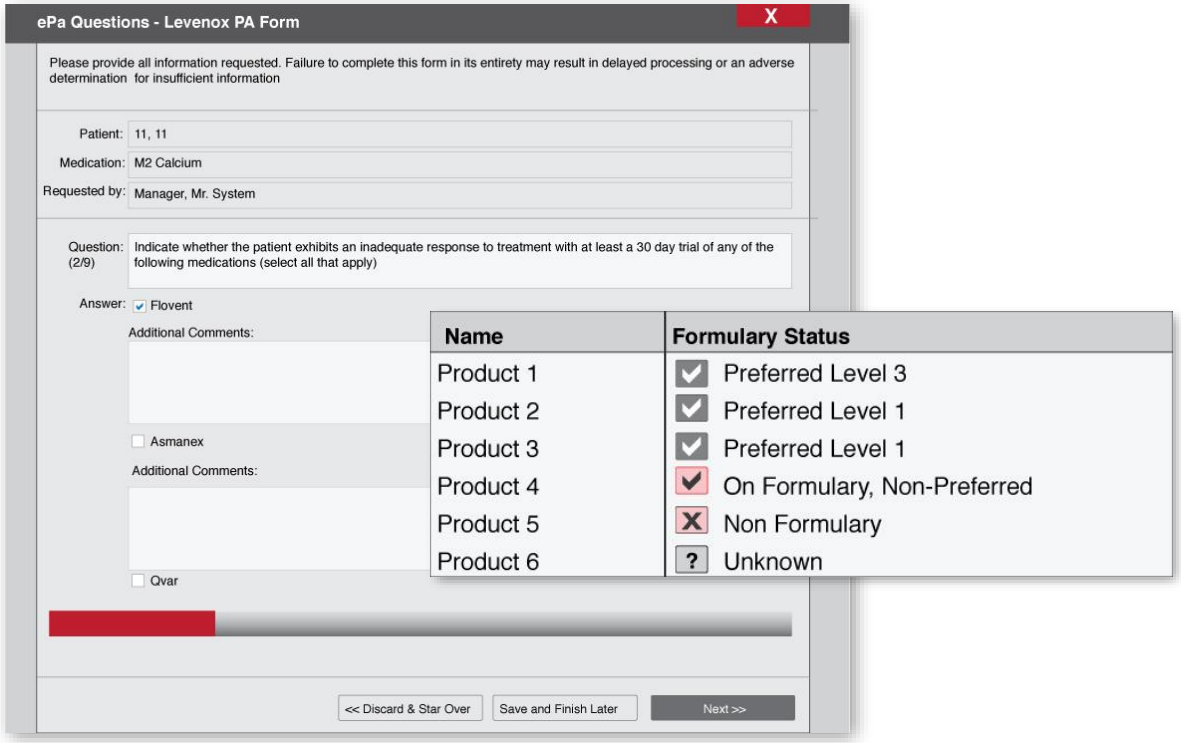
HCPs need to understand the patient's managed care formulary and payment policies

- Is the patient covered for a biosimilar
- Is a step edit and prior authorization required

EHRs display MCO formularies and policies within the clinical workflow

Its important to understand and educate HCPs on managing biosimilar MCO policies in the EHR

- Biosimilars are new; HCPs will need to be comfortable with MCO coverage before converting from a familiar reference biologic



Patients need to be educated and engaged to be successfully treated with a biosimilar

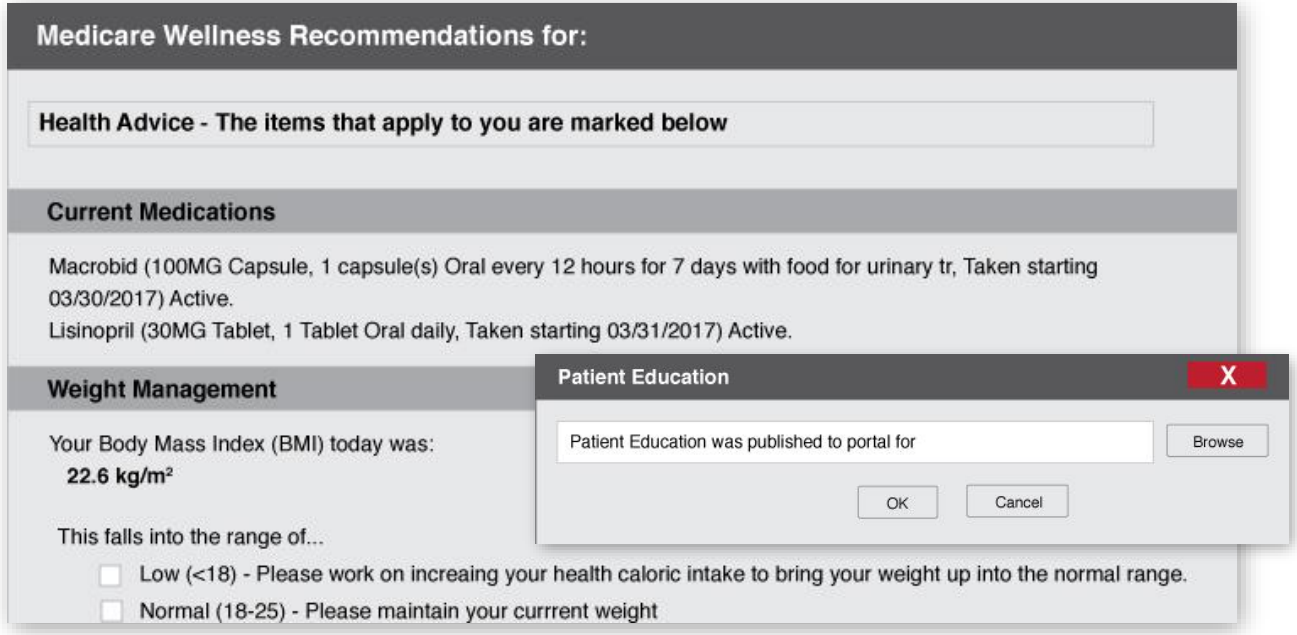
4. Patient Engagement

HCPs need to engage and educate patients for successful treatment

Patient education and engagement are now delivered through the EHR

HCPs need the ability to deliver patient education in the clinical workflow

Biosimilar manufacturers need to provide quality branded and unbranded materials with the ability to be delivered in the clinical workflow



A biosimilar EHR strategy that meets customer needs is executed in three phases

Point-of-Care Partners EHR Navigator®

1 Prior to Launch

- Map EHR Landscape to Brand Strategy and Target Market
- Research & Build EHR Timetable
- Prepare Compendia Drug File Submission
- Develop Internal Plans and Communications
- Develop Customer Resources
- Develop and Execute Training Curricula
- Prepare Helpdesk

2 At Launch

- Submit Compendia Drug File
- Engage EHRs
- Monitor & Communicate Updates to Timetable
- Launch Helpdesk, Track & Resolve, FAQs

3 Post Launch

- EHR Pull-Through
- Brand Awareness EHR Messaging
- Target Specific Patients with Clinical Decision Support
- Improve EHR Patient Engagement & Compliance
- ePrescribing Formulary Pull-Through
- eCoupon and Co-Pay

Biosimilar Customer Needs

1. Access in EHR
HCPs need to easily identify and prescribe a biosimilar in the EHR

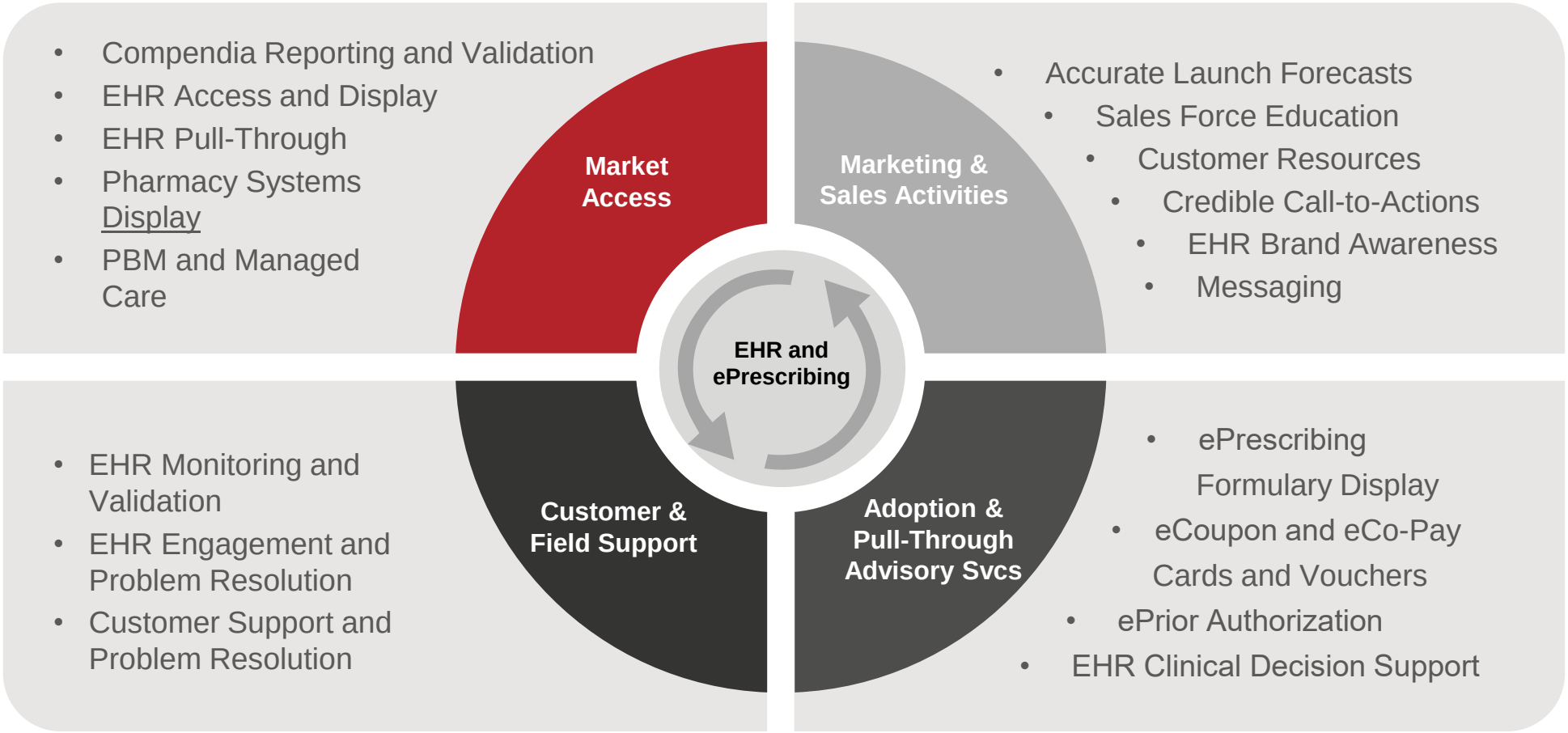
2. Prescribing
HCPs need to understanding how to correctly prescribe a biosimilar

3. Patient Information
HCPs need MCO formularies and prior authorization requirements

4. Patient Engagement
HCPs need to engage and educate patients for successful treatment

A comprehensive EHR engagement program is recommended for Biosimilar launch success

Point-of-Care Partners EHR Navigator®



- Compendia Reporting and Validation
- EHR Access and Display
- EHR Pull-Through
- Pharmacy Systems Display
- PBM and Managed Care

- Accurate Launch Forecasts
- Sales Force Education
- Customer Resources
- Credible Call-to-Actions
- EHR Brand Awareness
- Messaging

- EHR Monitoring and Validation
- EHR Engagement and Problem Resolution
- Customer Support and Problem Resolution

- ePrescribing Formulary Display
- eCoupon and eCo-Pay Cards and Vouchers
- ePrior Authorization
- EHR Clinical Decision Support

Contact Us

Telephone: (877) 312-7627

Pooja Babbrah: pooja.babbrah@pocp.com
Craig Kemp: craig.kemp@pocp.com
General Email: info@pocp.com

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