Introduction

• The Academy of Managed Care Pharmacy's Biologics and Biosimilars Collective Intelligence Consortium (BBCIC) was convened in 2015.

• BBCIC is dedicated to monitoring biosimilar safety and effectiveness utilizing large datasets (~30 million lives) with de-identified medical and pharmacy data.

• Data are extracted using cutting-edge distributed research network (DRN) and surveillance methods.1

• Descriptive and comparative analyses were undertaken of different originator compounds in the same class as well as originators and their corresponding biosimilars. The descriptive analyses are being undertaken to demonstrate technical feasibility and if so, comparative analyses will use the DRN to compare different originators with each other as well as originator and biosimilar products.2,3

• BBCIC leverages the FDA's Sentinel Initiative DRN, an active surveillance collaboration of 18 member organizations from managed care integrated delivery networks, pharmacy benefit managers, and the coordinating center (Harvard Pilgrim Health Care), to collaborate with industry sponsors.

• Participating BBCIC organizations include: AbbVie, Astra, Amgen, AMCO; Anthem Healthcare, ApoBio, Boehringer Ingelheim Pharmaceuticals Inc., Express Scripts Inc., HealthPartners, Henry Ford Health System, Kaiser Permanente Washington Health Research Institute, Optum, Sanford, and Harvard Pilgrim HealthCare.

• Public representation on the BBCIC Planning Board include the American Society of Clinical Oncology, American College of Rheumatology, and the National Health Council.

Methods

• Proposed studies are reviewed by the BBCIC Science Committee tasked with guidance over research plans, review of study applications, protocols, reports, and manuscripts.

• Descriptive analyses (DA) were conducted to understand patients, diseases, treatments, and outcomes.

• Comparative analyses are planned to assess originator biologic and biosimilar safety and effectiveness.4

Results

Table 1: 4 descriptive analyses (DA) have been completed and 4 workgroup projects are near completion. Outcomes are described below:

<table>
<thead>
<tr>
<th>Workgroup</th>
<th>Project Title</th>
<th>Outcomes</th>
</tr>
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<tbody>
<tr>
<td>Nov 2015</td>
<td>Convene and practice on CER methodology</td>
<td>Sparking CER methodology discussion.</td>
</tr>
<tr>
<td>Oct 2015</td>
<td>Establish the first CER project pilot project</td>
<td>Establish the first CER project pilot project.</td>
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<tr>
<td>Feb 2016</td>
<td>First CER project pilot project initiated</td>
<td>Initiate the first CER project pilot project.</td>
</tr>
<tr>
<td>Q3 2016</td>
<td>First 4 DA projects completed</td>
<td>Complete the first 4 DA projects.</td>
</tr>
<tr>
<td>Oct 2017</td>
<td>Convene and practice on CER methodology</td>
<td>Sparking CER methodology discussion.</td>
</tr>
<tr>
<td>Nov 2017</td>
<td>Establish the second CER project pilot project</td>
<td>Establish the second CER project pilot project.</td>
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<tr>
<td>Dec 2017</td>
<td>Start the second CER project pilot project</td>
<td>Start the second CER project pilot project.</td>
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</table>

Acknowledgements

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References


Conclusions

• Outcomes comparable to those in the published literature were demonstrated for 3 of 4 descriptive analyses: G-CSFs, long-acting insulins, and anti-refractomies.

• EDA data do not contain needed granularity and future research will employ alternative data sources.

• Descriptive analyses have uncovered gaps in data availability, structure, or other needs that led to the convening of workgroups.

• In preparation for the planned CER studies, convened workgroups are identifying best practices that will be implemented.

• Following sufficient descriptive analyses, efficacy analyses, and biosimilar exposures, CER studies will be initiated to assess the safety and effectiveness of biosimilars compared with their originator compounds.

Next Steps

• Identification of sources to enrich and fill data gaps identified by DA will continue.

• CER studies are planned for G-CSFs, insulins, and anti-refractomies in 2019.

• A descriptive analysis of trastuzumab is scheduled to begin in 2019.