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## A Note from the Executive Director

As 2020 comes to an end (finally?) it has been fun to reflect on the many accomplishments of our small but mighty consortium! Due to the pandemic we had fewer opportunities to present our work at scientific and professional meetings, this year, although we still presented four abstracts and presented on the podium twice and via webinar once. We have three manuscripts currently in peer-review, anxiously awaiting publication even with notably longer review periods at nearly every journal.

[Read the full letter.](#)

## 2020 Accomplishments: Manuscripts

**2 manuscripts currently in peer-review**

**Patient Characteristics and Utilization Patterns of Recombinant Granulocyte Colony Stimulating Factor (G-CSF) Biosimilars Compared to their Reference Product**

Aaron B. Mendelsohn, James Marshall, Cara L. McDermott, Pamala A. Pawloski, Jeffrey S. Brown, Catherine M. Lockhart

**Submitted to the Drugs – Real World Outcomes**

**1 manuscript published (for a total of 7)**

Zhang J, et al. **Incidence of Serious Infections and Design of Utilization and Safety Studies for Biologic and Biosimilar Surveillance.** *J Manag Care Spec Pharm.* 2020. Apr;20(4):417-490.

[View Manuscript](#)

**1 manuscript accepted**

**Utilization patterns and user characteristics for biologic anti-inflammatory agents in a large, US commercially**

## Looking to 2021

### Anticipated Manuscript Submissions

- G-CSF Scoping Review
- Oncology Data Feasibility
- G-CSF CER Methods/Protocol
- Trastuzumab Scoping Review\*\*
- Trastuzumab Utilization Analysis
- Bevacizumab Scoping Review – Breast Cancer\*\*
- Bevacizumab Scoping Review – AMD\*\*
- Bevacizumab Utilization Analysis

**Descriptive Analysis of First-Cycle Prophylactic Use of G-CSF in Patients with Breast or Lung Cancer Treated with High Neutropenia Risk Chemotherapy: Results from the BBCIC Distributed Research Network**  
 Pamala A. Pawloski, Cara L. McDermott, James H. Marshall, Vanita Pindolia, Catherine M. Lockhart, Catherine A. Panozzo, Jeffrey S. Brown, Bernadette Eichelberger

**insured population**  
 Aaron B. Mendelsohn, Young Hee Nam, James Marshall, Cara L. McDermott, Bharati Kochar, Michael D. Kappelman, Jeffrey S. Brown, Catherine M. Lockhart

**Submitted to Pharmacology Research & Perspectives**

Submitted to JNCCN

**2020 Accomplishments: Abstracts and Abstract Tracker**

3 abstracts presented

**Global Evaluation of Real-World Studies on Biosimilar Usage in Oncology**

Shyra G. Bias, Nkiruka Emezienna, Catherine M. Lockhart, Jamila Jorden, Paula J. Eichenbrenner

AMCP NEXUS. 2020 October 20-22, Virtual

[View Abstract](#)

**Longitudinal evaluation of characteristics, treatment patterns, and general outcomes among patients using granulocyte colony stimulating factors: a study by the Biologics and Biosimilars Collective Intelligence Consortium**

Catherine M. Lockhart, Cara L. McDermott, James Marshall, Aaron B. Mendelsohn, Pamala A. Pawloski, Jeffrey Brown. NCCN 2020 February 29, Virtual

[View Abstract](#)

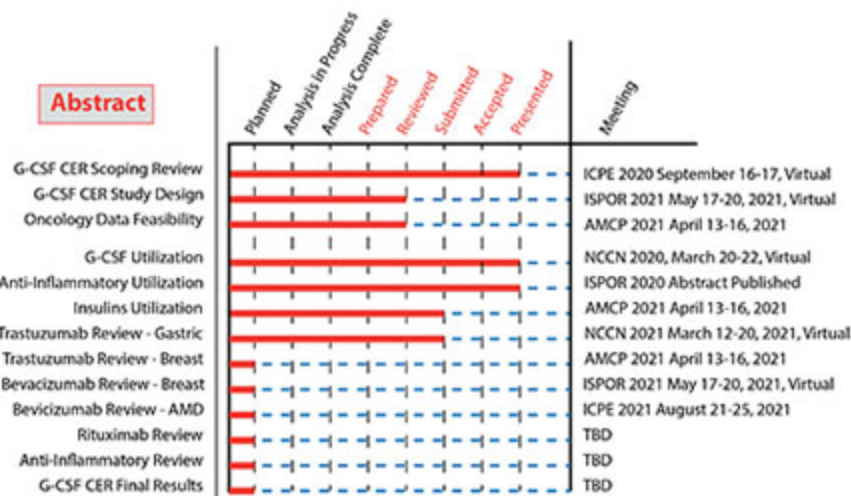
**Variation in evaluations of granulocyte colony stimulating factor use: a scoping review of observational studies**

Cara L. McDermott, Pamala Pawloski, Prasad Gawade, Cynthia Holmes, Edward Li, Aaron Mendelsohn, Gary C. Yee, Catherine M. Lockhart.

ICPE All Access 2020 16-17 September, Virtual

[View Abstract](#)

**Abstract Tracker:**



- Rituximab scoping review\*
  - Anti-Inflammatories scoping review\*
  - G-CSF CER Final Results
- Anticipated Abstract Presentations**
- NCCN – trastuzumab gastric cancer review
  - ISPOR – G-CSF CER methods/protocol
  - AMCP Annual – Insulins utilization analysis
  - AMCP Annual – Oncology data source review
  - AMCP Annual – Trastuzumab scoping review – breast cancer
  - ISPOR 2021 – Bevacizumab scoping review – breast cancer
  - ICPE 2021 – Bevacizumab scoping review - AMD
  - TBD – trastuzumab utilization analysis
  - TBD – bevacizumab utilization analysis
  - TBD – rituximab scoping review\*
  - TBD – anti-inflammatory scoping review\*
  - TBD – G-CSF CER Final Results

## 2020 Accomplishments: Podium Presentations and Research

### 2 podium presentations + 1 webinar

- Specialty Therapies and Biosimilars Conference – CBI/Informa (January, Miami, FL)
- Festival of Biologics World Biosimilar Congress (March, San Diego, CA)
- ISPOR Webinar (September)

### Research

#### 3 Utilization Analyses completed

- Granulocyte Colony Stimulating Factors
- Anti-Inflammatory Biologics
- Insulins

#### 2 Utilization Analyses in progress

- Trastuzumab
- Bevacizumab

## 2020 Accomplishments: Full-Scale Comparative Effectiveness and Safety Analysis in progress

### Co-Investigators

- Pamala A. Pawloski, PharmD, BCOP, FCCP — Senior Research Investigator, HealthPartners Institute
- Cara McDermott, MS, PharmD, PhD — Research Consultant, BBCIC

### Evaluating the comparative safety and effectiveness of G-CSF originator biologics (filgrastim, pegfilgrastim) and related biosimilars

- A comprehensive Scoping Review of the literature is being finalized to describe the current landscape of observational research in G-CSFs, to evaluate outcomes and methods use in other studies, and identify opportunities to address limitations in the existing body of literature
- The study design and protocol were approved by the BBCIC Science Committee in November 2020, and the Statistical Analysis Plan is being finalized
- Programming will soon be underway to gather data

## 2020 Accomplishments: Infrastructure project in progress — Oncology data feasibility and analysis

### Principal-Investigator:

Nancy Lin, ScD — Senior Scientist, Optum Epidemiology

### Feasibility assessment of available oncology data sources to enrich existing BBCIC capabilities in conducting research in oncology

- A feasibility and capabilities survey was submitted to 18 candidate data sources to evaluate:
  - Interest and willingness of the candidate data source/partner to collaborate with BBCIC
  - Feasibility (and research capability if relevant) of conducting BBCIC research

## BBCIC Research Priorities 2021 and beyond

### Research Studies

- Comparative safety and effectiveness of trastuzumab products
- Descriptive analysis of medication switching in rheumatoid arthritis
- Comparative safety and effectiveness of bevacizumab products
- Uptake, value, and reasons for utilization of biosimilars (incorporating novel data linkages and qualitative or mixed-methods research)
- Description of patient access to biologic treatment

### Methods/Infrastructure

- Development and validation of algorithms to identify cohorts in ICD9 vs ICD10 coding systems
- Methods and validation to identify metastatic disease in claims
- Recommended best practices for qualitative/mixed-methods research for BBCIC

### Utilization Monitoring and Descriptive Characteristics

*(no particular order – all will be conducted in 2021)*

- trastuzumab, bevacizumab,

- Capabilities in conducting research under the BBCIC framework
- Whether and how the BBCIC framework may need to change to accommodate the oncology research that we intend to pursue

7 responses were received

Summary, analysis, and recommendations are in preparation.

rituximab, anti-inflammatory, G-CSF, insulins

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