

Genomics Biotech & Emerging Medical Technologies Council (GBEMTI)

Executive Summary

History

The Genomics Biotech and Emerging Medical Technologies Council (GBEMTI) was formed in 2010. This is one of four institutes within the NAMCP Medical Director Institute. The institute began so NAMCP could advocate the value of genomics, biotech and medical technologies as these new modalities enter and impact the healthcare system and thereby improving patient outcomes, improving quality and bringing value to the market place. NAMCP Medical Directors acknowledged a need in the managed care marketplace for a *centralized entity* to address emerging health technology evidence generation, reimbursement and patient access.

In 2011, GBEMTI instituted an Executive Leadership Council (ELC) to begin looking at the pertinent issues within the Genomics, Biotech and Technologies world. The ELC consists of GBEMTI's corporate partners as well as medical directors from the purchasers, plans and provider systems. The institute is led by Eric Faulkner, Adi Renbaum and Daryl Spinner. The ELC meets twice a year at the Spring and Fall Managed Care Forums presented by NAMCP, AAMCN & AAIHDS. From this ELC, GBEMTI has produced many leading tools that help manufacturers understand how they can better their product which will ultimately improve patient outcomes.

NAMCP/GBEMTI Genomics Dossier Templates

1.) Medical Technologies Dossier: The purpose is to provide medical directors and manufacturers with a medical device dossier format that accounts for evidence development approaches and unique aspects of these technology types (versus simply following drug-based formats that may not be ideal for other types of health technologies). This format has been developed with Medical Directors and device providers working collaboratively to ensure that the format is the most useful, practical, and succinct for US payer decision making. Can be found at:

<http://www.namcp.org/journals/Medical%20Technologies%20Dossier.pdf>

2.) Medical Diagnostics Dossier: The purpose is to provide medical directors and molecular, genetic and other appropriate diagnostic test laboratories with a dossier format that accounts for evidence development approaches and unique aspects of these technology types (versus simply following drug-based formats that may not be ideal for other types of health technologies). This format has been developed with Medical Directors and test providers working collaboratively to ensure that the format is the most useful, practical, and succinct for US payer decision making. Can be found at:

<http://www.namcp.org/journals/Medical%20Diagnostics%20Dossier.pdf>

GBEMTI ELC Meeting Agenda Topics and Discussions

2011 Fall Forum GBEMTI ELC Meeting

- Began discussion on GBEMTI and what the purpose of the ELC was going to be.
- Discussed the purpose of the white paper on value based reimbursement model (s) for medical technology
- Discussed topics about:
 - current state of implantable medical devices
 - value based reimbursement for medical devices
 - barriers that exists for value based reimbursement implementation
 - ensured success for value based reimbursement models for medical devices
- Open discussion on next steps and Spring ELC topics

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2012 Spring Forum GBEMTI ELC Meeting

- Began discussion where we have been and where we are going
- Regenerative Medicine Overview
- Survey results and discussion on emerging medical device division, biologics and specialty division and diagnostics and personalized medicine
- Open discussion on next steps and Fall ELC topics

2012 Fall Forum GBEMTI ELC Meeting

- Goals, Objectives and History Overview
- Review of perspective paper timelines
- Feedback on Medical Device Value Based Reimbursement Paper
- Open discussion on next steps and Spring ELC topics

2013 Spring Forum GBEMTI ELC Meeting

- Background, Update and Review
- Aligning Evidence Development & Use in Managed Care Business Models
- Impact of Affordable Care Act Changes and Fixed Sequestration on Managed Care Models: How Should We Prepare?
- Open discussion on next steps and Fall ELC topics

2013 Fall Forum GBEMTI ELC Meeting

- Goals, Objectives and Update on Paper Timelines
- Discuss Personalized Medicine paper outline / figures
 - General comments from GBEMTI
 - Key implications/recommendations to be included
- Discussion on Managed Care issues and concerns with multi-analyte testing, panels and whole genome sequencing
- Open discussion on next steps and Spring ELC topics

2014 Spring Forum GBEMTI ELC Meeting

- Update on Institute
 - Personalized Medicine paper draft
 - Proposed Dossier Template for Medical Devices and Diagnostic Testing
- Discuss topics on:
 - Breakthrough Therapies: Addressing Perceived Evidence Gaps for Early Submission
 - How to address orphan/rare specialty populations
- Open discussion on next steps and Fall topics

2014 Fall Forum GBEMTI ELC Meeting

- Discussion and Update on Institute
 - Personalized Medicine White Paper being published
 - Regenerative Medicine White Paper being drafted
 - Dossier Template Launch and Next Steps
 - Update on Latest Survey and Initial Findings
- Open discussion on next steps and Spring ELC topics

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2015 Spring Forum GBEMTI ELC Meeting

- Discussion and Update on Institute
 - Regenerative Medicine White Paper Update
 - Dossier Template Update and Discussion
 - Corporate Partner Survey Questions
- Discuss topics on:
 - How managed care is evolving due to real world evidence
 - How managed care evaluation will evolve by utilizing IT and big data
- Open discussion on next steps and Fall ELC topics

2015 Fall Forum GBEMTI ELC Meeting

- Discussion and Update on Institute
 - Regenerative Medicine White Paper Update
 - Dossier Template Update and Discussion
- Discuss topics on:
 - Best Practices and Services Around the Product
- Company and Product Presentations
 - Biodesix
 - Boston Scientific
 - Exact Sciences

2016 Spring Forum GBEMTI ELC Meeting

- Discussion and Update on Institute
 - Dossier Template Update and Discussion
- Discuss topics on:
 - *The Evolving World of E-Connectivity: New Applications that Generate Important Data in the Managed Care World*
- Company and Product Presentations
 - BioFire Diagnostics
 - Counsyl
 - HeartFlow
 - Vermillion

2016 Fall Forum GBEMTI ELC Meeting

- Discussion and Update on Institute
- Discuss topics on:
 - *Flipping the World on its Axis: Implications of Health Reform Shifts in the Payer/Provider Power Balance on Novel Health Technologies*
- Company and Product Presentations
 - Acorda Therapeutics
 - BioReference Laboratories
 - Castle Biosciences
 - LIM Innovations
 - Natera

2017 Spring Forum GBEMTI ELC Meeting

- Discussion and Update on Institute
- Discuss topics on:
 - *The Price is Right? - Managed Care Views on Health Technology Pricing and Value Alignment*
- Company and Product Presentations
 - Epigenomics
 - Foundation Medicine
 - Myriad Genetics
 - Woundtech

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2017 Fall Forum GBEMTI ELC Meeting

- Discussion and Update on Institute
- Discuss topics on:
 - *What is Value and Where Can It Be Found within Innovative Partnerships?*
- Company and Product Presentations
 - AveXis
 - Genomic Health
 - Intersect ENT
 - Jazz Pharmaceuticals

2018 Spring Forum GBEMTI ELC Meeting

- Discussion and Update on Council
- Discuss topics on:
 - *The Impact of Medicare Advantage Trends on Adoption and Use of Medical Innovations*
- Company and Product Presentations
 - Biodesix
 - Boston Scientific
 - Neurocrine Biosciences
 - Vertos Medical

2018 Fall Forum GBEMTI ELC Meeting

- Discussion and Update on Council
- Discuss topics on:
 - *How Do Partnership Models Help Solve Complex Patient Management Issues?*
- Company and Product Presentations
 - Avedro
 - Leo Pharma
 - Pharming Healthcare
 - Turn-Key Health

2019 Spring Forum GBEMTI ELC Meeting

- Discussion and Update on Council
- Discuss topics on:
 - *The New Reality of Real World Evidence*
- Company and Product Presentations
 - Acesa Health
 - Bioventus
 - Senseonics
 - Zimmer Biomet

2019 Fall Forum GBEMTI ELC Meeting

- Discussion and Update on Council
- Discuss topics on:
 - *Innovative Value Demonstrations and Reimbursement Models: Best Practices to Show Where Are We Now?*
- Company and Product Presentations
 - Exact Sciences
 - Genomic Health
 - Mallinckrodt
 - UCB

2020 Virtual Spring Forum GBEMTI ELC Meeting

- Discuss topics on:
 - *Shaping Medical Policy: How Do Third-Party Guidelines and Evidence Reviews Influence Medical Policy Development?*
- Virtual Company and Product Presentation
 - Illumina

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2020 Virtual Fall Forum GBEMTI ELC Meeting

- Discussion and Update on Council
- Discuss topics on:
 - *COVID-19: Impact on the Healthcare Delivery System, New Technology, and US Managed Care*
- Virtual Company and Product Presentations
 - Epizyme
 - Exact Sciences
 - Jazz Pharmaceuticals
 - Leo Pharma
 - LivaNova
 - Optinose
 - Otsuka
 - Scipher Medicine
 - Supernus

2021 Virtual Spring Forum GBEMTI ELC Meeting

- Discussion and Update on Council
- Discuss topics on:
 - *Questions from the Industry Perspective: The Medical Director Role and their Influence on Managed Care*
- Virtual Company and Product Presentations
 - ChemoCentryx
 - CSL Behring
 - Exact Sciences
 - Integra Life
 - Nevro
 - Ocular Therapeutix
 - Verrica

2021 Fall Forum GBEMTI ELC Meeting

- Discussion and Update on Council
- Discuss topics on:
 - *Evolving Dynamics of Provider-Based Payer Programs*
- Virtual Company and Product Presentations
 - Daiichi Sankyo
 - Heron
 - Illumina
 - iRhythm
 - Otsuka
 - Sera Prognostics
 - Takeda
- Final Live Company and Product Presentations
 - Decipher/Veractye
 - Exosome
 - Myriad Genetics
 - Variantyx

2022 Spring Forum GBEMTI ELC Meeting

- Discussion and Topics on:
 - *Realigning Evidence & Coverage Processes: What is “The Way” for Innovative Technologies?*
 - *Exploring “Next Generation” Evidence & Coverage Through the Lens of Single Administration Therapies*
- Virtual Company and Product Presentations
 - Akili Interactive
 - Bridge Diagnostics
 - Cala Health
 - CareDx
 - Foundation Medicine
 - Genentech
 - Mainstay Medical
 - Mitsubishi Tanabe
 - NephroSant
 - Prometheus
 - Tandem Diabetes

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2022 Fall Forum GBEMTI ELC Meeting

- Discussion and Topics on:
 - *What We Have Learned & Insights for Coverage Policy Development*
- Virtual Company and Product Presentations
 - Binx Health
 - Boston Scientific
 - DermTech
 - Gilead
 - Karuna Therapeutics
 - Medtronic
 - Mirati
 - Novartis Pharmaceuticals
 - Optinose
 - Seagen
 - Sight Sciences
 - Stryker
 - Zimmer Biomet

2023 Spring Forum GBEMTI ELC Meeting

- Discussion and Topics on:
 - *Understanding Your Audience: Medical Director Role and How It Impacts You*
 - *Effectively Communicating to Medical Directors*
- Virtual Company and Product Presentations
 - AbbVie
 - Biodesix
 - GE Healthcare
 - Grail
 - ImmunoGen
 - Karuna Therapeutics
 - Lucid Diagnostics
 - Nalu Medical
 - Philips
 - Procept Biorobotics
 - Vertos Medical

2023 Fall Forum GBEMTI ELC Meeting

- Discussion and Topics on:
 - *Preparing Your Evidence for Medical Policy Review: A Policy Expert's Analysis Method and Best Practices*
 - *Streamlining the NAMCP Dossier: Framing Your Request by Highlighting Key Documents*
- Virtual Company and Product Presentations
 - Bionano
 - C2N Diagnostics
 - CareDx
 - Geneoscopy
 - Kaleo
 - Medtronic ENT
 - Mindera Health
 - Myriad Genetics
 - Nevro
 - Scipher Medicine
 - Sumitomo Pharmaceuticals
 - Takeda
 - Verrica Pharmaceuticals