

**2022 America's Got Regulatory Science Talent Competitions  
Presentation Abstracts & Student Biographies**

<b>University of Rochester</b>	
<b>1<sup>st</sup> Place Team</b>	<p><b>“Smart Event Evaluation and Reporting (SEER)”</b></p> <p>The FDA and medical product developers and manufacturers have a rich source of information made available to them through many diverse adverse event reporting platforms, but this wide selection results in a large quantity of data to parse through. This team outlined a regulatory initiative to make use of the data by passing it through a machine learning algorithm, SEER, that is designed to identify trends in the data throughout both the pre- and post-market timelines.</p>
<b>Team Members</b>	<b>Warish Zaman Orko and Mark Truskinovsky</b>
<b>Presentation Abstract</b>	<p>A variety of adverse event reporting initiatives exist, such as FAERS, MedWatch, VAERS, and MAUDE, to which medical professionals as well as individual medical product users are able to report adverse events that occur when engaging with a product. From FAERS alone there were almost 2.5 million reports in 2021, highlighting the vast availability of data which also comes with a steep time investment when looking to analyze it. Leveraging the power of machine learning to parse through large quantities of data and provide potentially meaningful conclusions from it, we propose the implementation of the Smart Event Evaluation and Reporting (SEER) initiative to help inform medical product developers of factors to take into consideration for existing product improvement as well as future product development efforts.</p>
<b>Team Member Bios</b>	
<b>Warish Zaman Orko</b>	<p>Warish Zaman Orko is a graduate of the University of Rochester’s Biomedical Engineering undergraduate program, and currently pursuing his M.S. in Biomedical Engineering from the Center for Medical Technology &amp; Innovation (CMTI) program at his alma mater. He is passionate about improving patient care in a safe, well-regulated manner and is looking to enter the medical device industry in a Quality/Regulatory role. Warish enjoys science fiction and skiing.</p>
<b>Mark Truskinovsky</b>	<p>Mark Truskinovsky received a B.S. from the Rochester Institute of Technology (RIT) in Biomedical Engineering after which he transitioned to the University of Rochester to receive an M.S in Biomedical Engineering through the Center for Medical Technology and Innovation (CMTI) program. Through his program at RIT, Mark has participated in several co-ops in internships with companies such as Biogen, Hikma Pharmaceuticals, and Teleflex, holding a variety of job functions. When working for Hikma Pharmaceuticals, Mark was an intern for the drug regulatory department and was assigned work characterizing the regulatory landscape for combinations products to develop standard operating procedures and other protocols for the company to follow.</p>