



International Alliance for  
Biological Standardization

## 9<sup>th</sup> Annual IABS Statistics Workshop

# Applying Statistics and Data Science to Evolving Technical and Regulatory Paradigms

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**Title: CAR T-Cell Therapy Data Long tails, mixtures, hurdles, censoring; definitively not normal**  
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Autologous chimeric antigen receptor (CAR) T-cell therapies are customized for each individual patient by re-engineering T-cells, so they can recognize and attack cancer cells, especially in the treatment of some hematologic malignancies. In contrast to a traditional biologics process, where batches, or lots, of multiple units are manufactured, in a CAR T-cell GMP (Good Manufacturing Practices) process, each individual patient is the lot. A CAR-T dataset is then a composite of many individual patients, and this creates interesting opportunities for industrial statisticians. In this talk we explore some of the unique differences of CAR T-cell therapy data, and how the over reliance on the normal distribution and transformations don't cut it anymore. We also discuss how the use of appropriate distributions and Bayesian techniques provide a useful methodology to gain insights from CAR T-Cell data.

