



## ENRICH: A Novel Approach to Clinical Trials in ICH

Tuesday, April 11<sup>th</sup>, 2023 • 6:00pm EST

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The ENRICH Trial has completed enrollment and many are anxiously awaiting the results. As ENRICH is the FIRST adaptive clinical trial designed with enrichment based on hemorrhage location, there are several questions surrounding this unique structure and how proper interpretation of results is essential for understanding the level of impact the data may provide. Are you curious to know:

*Why is trial design so important?*

*How is ENRICH different from other ICH trials?*

*Without p-values, how should data be interpreted?*

Join an expert in novel **Bayesian adaptive design and analysis**, Dr. Ben Saville, PhD as he discusses key aspects of the ENRICH randomized adaptive clinical trial including population enrichment, flexible sample size, and why primary results will be presented without p-values.

### Benjamin R. Saville, PhD

*Berry Consultants, LLC*

Director, Trial Design & Analysis  
Senior Statistical Scientist



Ben Saville specializes in the design of innovative Bayesian adaptive clinical trials, working primarily with medical device companies, pharmaceutical companies, and academic investigators. Through his work to solve challenging problems via Bayesian adaptive platform trial designs and related topics, Dr. Saville has authored approximately 100 peer-reviewed publications in the statistical and medical literature.

### PROGRAM AGENDA

#### Novel Adaptive Clinical Trials

*Landmark trials influencing patient care through adaptive design*

#### What Makes ENRICH Different

*Novel Bayesian adaptive design*

*Flexible sample size*

*Population enrichment*

*Innovative primary endpoint measure*

#### Interim Adaptations

*Advantages of population enrichment by hemorrhage location*

#### Bayesian Probabilities Instead of p-values

*Understanding the results of ENRICH*



Questions?

Q&A