

PhD program in Statistics

## DSS Statistics Seminar

**April 5, 2024, 12:00**

**In person** Room 24 (CU002)

**Webinar** [https://uniroma1.zoom.us/j/86881977368?pwd=SWRFc](https://uniroma1.zoom.us/j/86881977368?pwd=SWRFcVFjMDZTa0lXZk05TE1zNm5adz09)

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**Passcode: 432940**

External information borrowing  
in clinical trial hypothesis testing  
with controlled TIE rate inflation

### ***Silvia Calderazzo***

*Division of Biostatistics, German Cancer Research Center, Heidelberg*

When designing a novel clinical trial, external information about the control and/or treatment arm effect is typically available. Borrowing of such external information is often desired in order to improve the trial's efficiency, and can be of crucial importance in situations where the sample size that can realistically be recruited is limited, as, e.g., pediatric or rare disease trials. The Bayesian approach allows borrowing of such external information through the adoption of informative prior distributions. An issue associated with the incorporation of external information is that external and current information may systematically differ. However, such inconsistency may not be predictable or quantifiable a priori. Robust prior choices are typically proposed to avoid extreme worsening of operating characteristics in such situations. In this talk, we will focus on frequentist type I error rate and power. We will in particular consider how type I error rate is affected by incorporation of external information, and present a novel approach which allows a principled and controlled inflation. Both one and two-arm clinical trial designs will be considered.



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