

# Einladung zum ZeSOB Kolloquium

Am Montag, 20. Februar 2023, um 16:30 s.t. spricht Frau

**Dr. Cornelia Ursula Kunz**

(Boehringer Ingelheim Pharma GmbH & Co. KG, Global Biostatistics & Data Sciences)

über

## Advanced tumor metrics to support characterization of the dose-response relationship

Developing new drugs is often time-consuming and sometimes inefficient. Especially in oncology, clinical trials tend to be expensive and hence, there is a need to save time and cost and speed up the development process. Initiatives like the FDA's Critical Path Initiative aim at transforming the way FDA-regulated products are developed in general while the Oncology Center of Excellence Project Optimus specifically focuses on optimizing the dose selection process in oncology. Typically, Phase 2 trials in oncology are performed using binary outcomes like objective response with the drug entering Phase 3 if the response rate achieves some pre-defined criteria. Unlike in other therapeutic areas, there is no formal dose finding in the sense of establishing a dose-response relationship and selecting an optimal dose. One main question is whether other tumor measurements can be used in Phase 2 trials to characterize dose-response relationships. Tumor growth models which describe the change of the tumor burden using exponential models could provide alternative measures, as for example the  $g$ (rowth)-rate or the  $d$ (ecline)-parameter.

Based on the exponential tumor growth models, we investigate the mathematical properties of the models and derive several equations and algorithms linking the  $g$ - and  $d$ -parameters to other tumor measures like response and progression as well as time-to-response, time-to-progression, and duration of response. The mathematical framework allows us to specify constraints like desired response rate, follow-up-time, and median time-to-response. Using these constraints leads to unique solutions for the mean of the logarithm of the  $g$ - and  $d$ -parameter. Based on this, the framework can be used to jointly simulate response and time-to-event endpoints in oncology. We investigate the advantages and disadvantages of using the  $g$ - and  $d$ -parameter instead of the response rate for establishing a dose-response relationship in Phase 2.

**Der Vortrag findet statt am Montag, 20. Februar 2023, um 16:30 Uhr s.t. im Seminarraum des KKSb an der Universität Bremen, Linzer Straße 4, 28359 Bremen.**

**Alle Interessierten sind herzlich willkommen!**  
(Einladungsvorschlag von Prof. Dr. Werner Brannath)