



## Human Radiolabeled Mass Balance (hAME) Studies for Regulatory Submission Part II: Understanding Human Mass Balance and Metabolite Profiling

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Join Fred and Diane as they discuss typical analytical aspects of formulation analysis in relation to an hAME study. Reserve your spot today, limited space is available for Part II in this series.

### Overview:

An hAME study typically covers two analyses for mass balance, 1) before dosing: the analysis of the formulation and dosing samples, and 2) after dosing: the analysis of the human blood, plasma, feces, and urine samples. Mass balance determines the amount of radioactivity dosed to the subject compared to the amount excreted. This main analytical objective determines the excretion and clearance profiles for total radioactivity in blood, plasma, urine and feces. Another objective is to determine the recovery values (percentage of the dosed radioactivity) which, in relation to the discharge criteria, define when subjects are allowed to leave the clinic.

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Join Us On  
May 27th, 2021  
(For East Coast US & EU)  
9am EDT | 15:00 CEST  
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