



1643 Spruce Street, Boulder, CO, 80302, USA
Phone: 1 303 440 8524, Fax: 1 303 440 032

**Course program: Quantitative Risk Analysis 3-Day Workshop:
Application to translational research in drug development
Research Triangle Park, NC**

Participants are encouraged to prepare for the class by reviewing this [document](#). However, this is not a pre-requisite for attendance.

The course runs from 09:00 to 17:00 each day, but **registrations on the first day begin at 8:30am**. Morning and afternoon coffee and lunch are provided. The course will be delivered in English.

<i>Day 1</i>	Background required: Basic quantitative background is required as no equations or mathematical results will be derived. However, basic R skills would be helpful to avoid spending too much time learning the R software rather than focusing on and learning QRA concepts. A list of basic R knowledge for participants to study prior to the class will be provided prior to the training.
<i>Module 1 Content</i>	Foundations of quantitative risk analysis methods for translational research in drug development <ul style="list-style-type: none">• Introduction to the course – topics to cover and special interest from participants• Introduction to risk analysis and MC simulation• Introduction to distributions in modeling – frequency, randomness, and uncertainty• Visualizing probabilities• Stochastic process refresher:<ul style="list-style-type: none">○ Binomial process, beta distribution, and numerical integration○ Poisson process, Gamma, Poisson, and Mixture distributions○ Distribution identities Objectives: After completing this module, participants will: <ul style="list-style-type: none">• Have a working knowledge of the methodology used in quantitative risk assessment in translational research in drug development, including basic probability theory, stochastic processes, and Monte Carlo simulation• Be able to independently develop simple quantitative risk assessment models



Sound answers for complex decisions

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<p><i>Days 2 & 3</i></p>	<p>Background required: Attendance to module 1, or alternatively working experience in quantitative risk assessments of intermediate complexity.</p>
<p><i>Module 2 Content</i></p>	<p>Applications of quantitative risk analysis methods for translational research in drug development</p> <ul style="list-style-type: none">• Fitting distributions:<ul style="list-style-type: none">○ Dealing with early clinical trial data○ Modeling expert opinion○ Using estimates from the literature• Modeling uncertainty:<ul style="list-style-type: none">○ Classical statistics○ Frequentist versus Bayesian Analysis<ul style="list-style-type: none">▪ Credible vs. confidence interval, fixed vs random parameters▪ Bayesian estimation methods: Manual construction, MCMC, ABC• Sensitivity analysis• Example applications in early drug development <p>Objectives: After completing this module, participants will:</p> <ul style="list-style-type: none">• Have a working knowledge of applied methodology used in quantitative risk assessment in translational research in drug development.• Be able to independently develop quantitative risk assessment models of introductory to intermediate complexity

The instructor will use practical examples to illustrate and reinforce the concepts and techniques that are presented. Time will be reserved to solving problems and/or working on group exercises and discussion. The software used for this training will be primarily the R statistical language, but when relevant or useful for teaching purposes, @RISK with Excel® may also be used.