



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

Course program*: [Risk Modeling in Drug Development](#)

EpiX Analytics, Boulder, CO

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. A social event will be provided at the beginning of the course. The course will be delivered in English.

<i>Day 1</i>	Welcome and general introduction Introduction to risk analysis in drug development <ul style="list-style-type: none">○ The use of qualitative and quantitative approaches○ Applications and real-life examples of risk analysis in drug development Why and how to do risk analysis <ul style="list-style-type: none">○ Fundamentals of Monte Carlo simulation and probability theory○ Calculation vs. Monte Carlo simulation Getting started with @RISK/Crystal Ball/Monte Carlo software <ul style="list-style-type: none">○ Monte Carlo simulation, Excel add-ons (@RISK® and Crystal Ball)○ Example/exercise: Modeling medical risks (e.g. Phase I – III, FDA approval) Probability distributions: <ul style="list-style-type: none">○ Mean, mode, standard deviation, percentiles, etc.○ Relative vs. cumulative, discrete vs. continuous distribution○ Graphical representations of risk events○ Example/exercise: C-max estimation at a certain dose Important techniques for modeling risk in drug development <ul style="list-style-type: none">○ Most appropriate distributions to use○ Two important stochastic processes, and their distributions and applications<ul style="list-style-type: none">● Binomial process● Poisson process● Example/exercise: Comparing side effects in a Phase III trial – a Bayesian approach
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Sound answers for complex decisions

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<i>Day 2</i>	<p>Risk modeling and decision making</p> <p>The use of expert opinion and historical data:</p> <ul style="list-style-type: none">○ Expert opinion distributions○ Expert opinion eliciting○ Best practices, types of biases, and how to prevent them○ The use of P10's and P90's○ Example/exercise: Combining IC50 values in a pharmacokinetics and dynamics (PK/PD) model <p>The use of data in risk analysis</p> <ul style="list-style-type: none">○ Fitting distributions to data <p>Uncertainty versus variability:</p> <ul style="list-style-type: none">○ Parameter uncertainty versus variability <p>Interpreting and presenting results:</p> <ul style="list-style-type: none">○ Typical risk analysis results, their presentation and correct interpretation○ Good modeling practices and common mistakes○ Comparing options using risk analysis○ Critiquing a risk analysis○ Example/exercise: Comparing the efficacy and side effects of two or several competing drugs based on limited data <p>Discussion of participants' modeling problems</p> <p>Delivery of certificates of attendance and adjourn</p>
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*The program might be slightly modified based on relevance to audience.