

# Biomarkers and Subgroups

Friday June 24, 2016, Leiden (NL)

*Biomarkers are increasingly present in modern drug development. They can be used as predictive or prognostic markers, and ideally will help scientists understand why a patient responds in a particular way to treatment. When biomarkers are used to identify sub-groups of patients who are likely to benefit from new therapies, a whole host of challenges arises, and many of them are of a statistical nature:*

- *How should biomarker development be included in clinical development planning?*
- *What do regulators expect to see to support a biomarker-based indication?*
- *How should we design a study that aims to identify a sub-group of patients with enhanced treatment effect, and what needs to be done to confirm this effect?*
- *What statistical methods are there to deal with these situations?*

*In this meeting, experts from industry, academia and regulatory agencies will come together to discuss these challenges, with a focus on practical applications*

## Draft Agenda

<b>8:00 – 8:55</b>	<b>Registration</b>
<b>8:55 – 9:00</b>	<b>Welcome</b>
<b>9:00 – 9:45</b>	<b>Hans-Ulrich Burger (Roche)</b> <i>Sub-Group Selection for Biomarkers – an Overview</i>
<b>9:45 – 10:30</b>	<b>Norbert Benda (BfArM)</b> <i>Regulatory View on Biomarkers and Subgroups</i>
<b>10:30 – 11:00</b>	<b>Coffee</b>
<b>11:00 – 11:45</b>	<b>Andrew Grieve (ICON plc)</b> <i>Adaptive Study Design for Subgroup Selection</i>
<b>11:45 – 12:30</b>	<b>Tim Friede (University Medical Center Göttingen)</b> <i>Methods for Exploration and Confirmation of Subgroups</i>
<b>12:30 – 13:30</b>	<b>Lunch</b>
<b>13:30 – 14:00</b>	<b>Andrew Stone (AstraZeneca)</b> <i>Including Biomarkers in Clinical Development Plans</i>
<b>14:00 – 14:30</b>	<b>Sebastian Jobjornssen (Chalmers University)</b> <i>Optimal Trial Design for Targeted Therapies</i>
<b>14:30 – 15:00</b>	<b>Coffee</b>
<b>15:00 – 15:30</b>	<b>Xavier Benain (Sanofi)</b> <i>Statistical Challenges in Diagnostic Biomarker Qualification</i>
<b>15:30 – 16:00</b>	<b>All Speakers</b> <i>Panel Discussion</i>
<b>16:00</b>	<b>Close</b>



## Venue

Astellas Pharma Europe B.V.,  
Sylviusweg 62,  
2333BE Leiden,  
Netherlands

## Registration Costs

Fee includes lunch & refreshments

Industry	€190
Academic	€120
Students	<i>a limited number of places is available free of charge, please contact the organizers</i>

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Note that there is limited parking space. Public transport is recommended