Thursday, May 23rd in Heidelberg, NH Hotel, Bergheimer Str 91, 69115
Friday, May 24th in Berlin, PAREXEL, Am Bahnhof Westend 15, 14050

SPEAKERS:

Olaf Ritzeler	Director of Scouting External Opportunities, ***SANOFI***
Dmitrij Hristodorov	Senior Director, Business Development & Licensing, ***BAYER***
Matthias Grossmann	Vice President & Principal Consultant, ***PAREXEL***
Laura Iavarone	Scientific Director, Quantitative Clinical Development, ***PAREXEL***
Bridget Heelan	Vice President, Regulatory Services, ***PAREXEL***
Keith Chidwick	Vice President, Regulatory Services, ***PAREXEL***
Silvia Maria Lavezzi	Scientist, Quantitative Clinical Development, ***PAREXEL***

AGENDA:

Time	Presentation / Topic
09.45 – 10.00	Welcome Coffee & Registration
10.00 – 10.10	PAREXEL Welcome & Introduction
10.10 – 10.50	Risk assessment for first in human studies – an investigator's perspective (Matthias Grossmann)
10.50 – 11.30	Quantitative clinical development for first in human studies (Laura Iavarone and Silvia Maria Lavezzi)
11.30 - 11.50	Coffee break
11.50 - 12.30	CMC requirements, expectations of the regulatory authorities and what to avoid – focus on biologics (Keith Chidwick)
12.30 - 13.15	Networking Lunch
13.15 - 14.00	Global expedited regulatory pathways and EU scientific advice (Bridget Heelan)
14.00 – 14.45	What a potential pharma licensing partner is looking for (Olaf Ritzeler in Heidelberg and Dmitrij Hristodorov in Berlin)
14.45 – 15.00	Closing remarks

Registration: Martina.Docherty@parexel.com

** Next Symposium in this series will be in October – Details to Follow*