CDx, NGS & Regulation – Webinar & Workshop

The Pistoia Alliance is examining the challenges of the **Development of Faster, Safe, Regulatory-compliant, Companion Diagnostics (CDx) using Next Generation Sequencing (NGS).**

Can the data standards and methods used in the research environment be aligned better with the data standards and methods used in the regulated environment? If so, the time and cost of the development of safe NGS-based CDx could be reduced.

Workshop – Wednesday 11th April: The Pistoia Alliance **CDx, NGS & Regulation Workshop** at **the Royal Society of Chemistry**, **Piccadilly, London.**

Speakers will introduce different perspectives on this challenge viz:
Regulatory Agency - Stephen Lee, Senior Regulatory Policy Manager, **MHRA**
Quality in Genetic Testing - Simon Patton, **EMQN**
Notified Bodies - Liz Harrison, Technical Team Manager, **BSI Group**
Pharma - John Whittaker, VP Target Discovery, **GSK**
CDx - Stewart McWilliams, VP Quality & Regulatory Affairs, **Almac**

and breakout sessions involving all workshop delegates will attempt to identify opportunities for pre-competitive collaboration to address some of these optimisation opportunities.

*Please **Register** your interest in attending the workshop*

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Workshop – AGENDA

11th April 2018, Royal Society of Chemistry, London

Morning Session		Afternoon Session	
09:00	Registration and Coffee	14:00	Industry Regulatory – Perspectives Challenges of NGS Companion Diagnostics Development (***Stewart McWilliams, VP Quality & Regulatory Affairs, Almac***)
10:00	Overview of the day and planned outcomes (***Mike Furness, Pistoia Alliance***)	14:30	Cross-Expertise Delegate Breakout Groups ***(chair: Nadia Anwar, Translational Research Solution Consultant, Oracle)*** *> What benefits could aligning the data requirements and standards bring?* *> What needs to be achieved to facilitate this?* *> Identify possible next steps*
10:30	Overview of current large-scale NGS data projects (**John Whittaker, VP Target Discovery, GSK**)		
11:00	Coffee	15:15	Coffee
11:30	What are CDx and the regulatory requirements around them? (***Stephen Lee, Senior Regulatory Policy Manager – IVD Devices Division, MHRA***)	15:45	Plenary session: Collect ideas, identify next steps and define targeted outcomes
12:00	How good is your Next Generation Sequencing? **(*Simon Patton, European Molecular Genetics Quality Network (EMQN))***	16:30	Networking Reception
12:30	Notified Bodies – what are they and what do they do? ***(Liz Harrison, Technical Team Manager, BSI Group)***	17:30	Close of Workshop
13:00	Lunch		

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