

Mahajan, Vinay

From: Baumann Brom, Stephan on behalf of Morris, David-1
Sent: Wednesday, February 24, 2016 7:49 PM
Subject: Keeping the COAR community informed: enhancing our organization



Dear Colleagues,

Few weeks ago, Vas announced the next steps to create the most powerful and most efficient drug-development engine in the world. This plan to enhance how we work will build on the success of our organization and maximize collaboration across the divisions. We would like to keep you posted on the changes we are implementing to achieve this goal.

What is new for the COAR community?

Part of this journey is the creation of a new group-wide Clinical Operations team (data management, statistical programming & medical writing). Formed from Pharma, Sandoz and Alcon capabilities, this new group will aim to revolutionize the Novartis Clinical Operations practices by becoming the most innovative and effective in the Industry to benefit our patients.

How are we defining the new group-wide Clinical Operations?

Five work streams with representatives from all divisions have been created to prepare the integration of Global functions into Novartis Global Drug Development organization and to maintain in-depth connectivity with respective trial management, trial monitoring, statistic and clinical functions. Some of you may be contacted to support them on their respective tasks.

Work Package	Lead	Co-lead	Top Objectives
Data Management	Jason Raines (Alcon)	Demetris Zambas (Oncology)	<ul style="list-style-type: none">• Define end-state organizational structure• Define approach to standard setting and

Stat Programming	Darren Weston (GenMed)	Insa Gathmann (Oncology)	governance (e.g., systems, processes) • Conduct in-depth review and rationalize processes cross divisionally • Implement / shift to one organization
Medical Writing	Stephen Eason (GenMed)	Jean-Marc Boulaire (Oncology)	
Oversight / Processes with Clin Ops Unit			
<i>Trial Operations</i>	Marie- Claude Raymond (Oncology)	Yen-Ching Chua (Sandoz)	• Conduct in-depth review of processes with Clin Ops unit and divisions ensuring & maintaining in-depth connectivity with functions and new unit. • Harmonize development functions standards, systems performance & KPIs
<i>Biostatistics/ Pharmacometrics</i>	Eric Gibson (GenMed)	Kannan Natarajan (Oncology)	
Baselining, synergies & process improvement	Dan Dietrich (GenMed)	Kala Subramanian (Oncology)	• Review central systems • Identify opportunity for process improvement

What is expected from you?

Looking at the year ahead, we need to maintain our focus on our development programs to ensure we deliver for our patients. With this in mind, our priorities and objectives stay the same for the COAR organization, as outlined below:

Focus areas for 2016

- 1 Support the delivery of priority trial objectives** and implement all Corrective and/or Preventive Actions (CAPAs) and quality plan deliverables
- 2 Roll out Future of Monitoring at Novartis (FOM@N) initiative** to ensure efficient and effective monitoring
- 3 Maximize the power of data** through roll out of eSource and electronic informed consent across the Development portfolio.

What is next?

Please stay tuned. We will continue to update you on regular basis through newsletters, local meetings and town halls.

Dave

