

From: Hines, Charlotte (Ext) on behalf of Communications, GDO (Gen)
Sent: Monday, March 04, 2019 4:41 PM
Subject: Reporting & Analysis Process Recalibration - Guidance Documents

Dear colleagues,

In 2018, we launched the [Streamlined Analysis Reporting and advanced ExplorATion \(SMART\)](#) initiative to drive our organization to focus clinical study reports (CSRs) consistently on key clinical trial questions, complemented by real-time data visualization and exploration. As part of SMART, the Reporting and Analysis Process (RAP) Recalibration work stream embarked on a journey to assess the trial reporting process and propose necessary changes that would enable streamlined analysis & reporting and advanced exploration. The RAP Recalibration work stream is pleased to roll-out guidance materials to facilitate the preparation of more streamlined CSRs:

- (1) [Guidance for CSR Listings](#)
- (2) [Guidance for In-text vs Post-text Outputs](#)
- (3) [Guidance for Abbreviated / Short Close-out CSRs](#)
- (4) [Guidance for Exploratory Analyses](#)

Is this guidance documents applicable to all CSRs?

Yes, the guidance documents are applicable for all Novartis global studies, whether in NIBR, GDD or GMA, and representatives from each of these organizations were part of developing the guidance.

Once we are writing the CSR, is it too late to apply the new guidelines?

The planning for a streamlined CSR should start with the Protocol and Statistical Analysis Plan (SAP) development. In 2018, the SAP LEANing work stream, also part of SMART, shared the SAP LEANing principles with trial statisticians and other key roles involved in the development of these deliverables. Teams are already incorporating these principles into their study planning, but for studies that are ongoing or CSRs already in draft, there is no expectation to completely overhaul the approach if these principles were not applied.

Please refer to the [SAP LEANing workshop slide deck](#) for a refresher on these principles.

What is expected from you?

Familiarize yourself with these guidance documents and use them for future RAP document development and CSR planning.

If I have questions, who should I contact?

Please reach out to any of the team members who contributed to the guidance materials.

RWS Contact List

[Leila Virkki](#)

[Judith Calderwood](#)

[Melissa Mohan](#)

What is next?

Detailed information on next steps can be found in the guidance materials. The major objective for RAP Recalibration in 2019 is to plan for the transition of the responsibility for tables, figures and listings shells creation to Statistical Programming. In the period leading to full transition in 2020, the Trial Statistician and Trial Programmer will start co-developing tables, figures and listings shells.

Best regards,
The RAP Recalibration Team

Sent to: All GDO

