

GSubP Performance Indicator (draft)

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Background

- “Regulatory convergence” has been a priority among APEC economies for needed patients to have early access to innovative medical products.
 - The regulatory Harmonization Steering Committee(RHSC): Established in 2009
- Good Registration Management (GRM) is the concept to promote both Good Review Practice (GRevP) by regulators and Good Submission Practice (GSubP) by industry cooperatively.
 - The goal: Enhance mutual trust for regulatory convergence among APEC economies by 2020.
 - Implementation of GRM concept: Stepwise implementation
- The activity to promote GSubP was initiated in 2013 by APAC.
 - Purpose: Improving the quality of registration/submission.
 - Next Step: Performance indicators should be examined to assess the effectiveness as GRM roadmaps



Concept of GRM

Specific Activities and Timeframe

Step 2: 2011-2016

Planned solutions to address GAP in GRM



Step 1 : 2011-2012

Gap Analysis Survey for setting the foundation for Stepwise GRevP Implementation

Step 3: 2017-2019

Assessing impact of GRM

- *Assessing the impact of training and implementation of GRevP, GSubP and GRM*
- *Dissemination of GRevP, GSubP and GRM*

Step 4: 2018-2020

Reaching the Goal for Implementing GRM

Performance Indicators

- Based on the needs of each economy, different measures may be taken to reach the same goal; therefore, in accordance to step 3 of the GRM roadmaps, performance indicators should be examined to assess the effectiveness of this roadmap in promoting GRM.
- GRevP performance indicators for authorities and GSubP's performance indicators for applicants will merge as GRM performance indicators (GRM KPI).
- GRM KPI will be evaluated periodically and comprehensively after initial roll out.

Performance Indicators for GSubP

Roadmap Outputs

- Below is a checklist of deliverables upon the successful completion of this roadmap:
 1. APEC GSubP Guideline Document for Applicants
 2. Training curriculum and materials or e-learning targeting on training of applicants
 3. Trainer's manual or handbook (Instructions for trainers on how to conduct training for applicants)
 4. Related documents based on each step of the roadmap such as survey report and progress report
 5. Final assessment reports on the impact of this roadmap in promoting GSubP

Measurable Outcomes

- *Applicants Competency and Training*
 - Implementation of technical training programs and soft skills training
 - Number of training certificates issued for qualified trainers
 - Number of training certificates for applicants
- *Quality of Submission (potential evaluation item)*
 - Number of major deficiencies/rejection at filing
 - Number of SOPs and templates available
 - Degree of adherence to each item of the principles of good submission

GSubP Performance Indicators (draft) (1/2)

Elements	Performance Indicators
Applicants Competency and Training	Implementation of technical training programs and soft skills training <ul style="list-style-type: none"> • Number of GRM CoE workshop • Number of local training in each economy
	Number of training certificates issued for qualified trainers <ul style="list-style-type: none"> • Number of people who have received the CoE training certificates • Number of workshop participating economies
	Number of training certificates for applicants <ul style="list-style-type: none"> • Number of participants in local training
Quality of Submission - Evaluation with measureable outcomes	Number of major deficiencies/rejection at filing <ul style="list-style-type: none"> • Number of major deficiencies at filing • Number of rejections at filing • Number of inquiries during review period
	Number of SOPs and templates available <ul style="list-style-type: none"> • Number of GRM tools available • Number of SOPs available

GSubP Performance Indicators (draft) (2/2)

Elements	Performance Indicators
Quality of Submission - Subjective evaluation	<p>Degree of adherence to each item of the principles of good submission</p> <ul style="list-style-type: none">• Compliance status of the "five key principles of good submission"<ul style="list-style-type: none">- Self evaluation to each of "GSubP five key principles"• Satisfaction level of the submissions<ul style="list-style-type: none">- Self-evaluation of the quality of the submission by applicants- Satisfaction level of the submission evaluated by reviewers
	<p>Period necessary for reviews</p> <ul style="list-style-type: none">• Duration of IND submission to IND open• Duration of NDA filing to approval<ul style="list-style-type: none">- The ratio of "too-long review" submission may indicate the ratio of poor-quality submissions

Future Plans

Activities	Timelines
• Introduce GSubP performance indicators (including draft questionnaire)	April, 2018
• Align GSubP performance indicators with GRevP performance Indicator (GRM KPI)	May-Jul, 2018
• Finalize GRM KPI and questionnaire	Jul, 2018
• Roadmap update in SOM 3 meeting	Aug, 2018
• Roll out GRM KPI questionnaire in line with APEC RHSC activities	Sep, 2018

Thank you!