SANDOZ A Novartis Division

Frequently Asked Questions

GEMS for IITs

May 2021

General

What is the Sandoz definition of an Investigator Initiated Trial (IIT)?
Sandoz defines IITs as "studies with scientific and medical merit developed and sponsored by either institution (academic or governmental) and individual investigators or groups of investigators. An IIT may be a clinical or non-clinical study conducted without the participation of Sandoz, for which the IIT sponsor requests Sandoz to provide either funding, drug product or both."

Why does Sandoz support IITs?
Sandoz believes in the need to support ethical independent clinical research conducted by qualified third-party investigators. The value of the scientific research produced by these investigators is key to complementing Sandoz-sponsored research by helping to ensure we better understand the benefit/risk profile of our therapies, as well as enabling us to explore new opportunities addressing unmet medical needs.

How does one submit an IIT for consideration?
All Sandoz IIT requests are submitted within the **G**rants, **E**xternal Studies and **M**anaged Access **S**ystem (**GEMS**) portal.

What is GEMS?
The GEMS portal is a global, cross-functional, cloud-based system to manage Investigator Initiated Trial (IIT), Managed Access Program (MAP), and Grant requests from end-to-end using the CyberGrants platform. "End-to-end" is from receipt of request to final delivery of either drug, or payment, or both, and the process of which may also include integration of certain Sandoz/Novartis systems.

Roles, responsibilities and training

What is the difference between the Request Owner (RO) and the Country Medical Responsible (CMR)? Can the RO and CMR be the same person?
The RO is responsible for the administration and oversight of the request from submission to closure. The CMR is responsible for some of the review and approval stages. However, dependent on the country organization and/or local procedures, RO and CMR roles/tasks may be executed by the same person.

Who assigns regional and global review roles, or are they assigned automatically?
The assignment of reviewers is carried out by the RO who selects the appropriate reviewer(s) from a list available in GEMS.

Can a Request Owner be changed?
Yes, there is the option to reassign a different RO at any point during the review and approval process of the request or during an ongoing study.

Who is the RO for Globally managed IITs? Is it the Global Medical Responsible (GMR) from the requestor's country?
The GMR is not assigned as a RO. However, if an IIT is globally or regionally managed the GMR may be assigned to carry out the same steps as a CMR.

Is it possible to have two user roles in the system simultaneously?
If a user has more than one role in GEMS (e.g. they are both an IIT and MAPS User), it is possible to toggle between different programs. Please refer to the GEMS for IITs User Guide for instructions.

Is an account set up automatically following completion of training?
Yes, you will receive an email within approx. two working days of fully completing your training which includes a link to GEMS. Once the system is live, you will be able to access GEMS.

Who do we contact for assistance regarding account setup?
The GEMS support team contact is Ginugu, Srinath (Ext) srinath.ginugu@novartis.com.

Is it possible for someone undertaking the Viewer e-learning to later undertake a different e-learning, such as Request Owner?

Yes. Anyone can take one or more e-learnings, however they will have GEMS user access based on defined functional role.

Is the Country Medical Responsible account for GEMS for Managed Access Programs (MAPs) also valid for IITs?

No, each of the GEMS applications (MAPs, Grants, IITs) is separate, as are the user roles. Also, please note that the user roles across GEMS applications might have the same name but a different scope of activities.

Do I need to perform additional training to access GEMS for MAPs?

Yes, access is only granted once the relevant user training for each program has been completed in Up4Growth.

Integration with CREDI/SUBWAY, IMPACT, HORIZON, CLEAR and GMA Vision

Will CREDI / SUBWAY continue to be used post GEMS for IITs Go-Live?
Following the global launch of GEMS, CREDI/SUBWAY will no longer be used for IITs. IIT documentation will be kept in GEMS with one exception: for integrated IITs the DSUR (Drug Safety Update Report) is filed in CREDI/Subway and not in GEMS.

How can we access CLEAR®?
Publications can be uploaded to CLEAR® via this link: FME Forum - Home (novartis.net). Scroll down to the section for CLEAR® under Publication Management Systems; Datavision® and CLEAR®

Is the upload of the publication carried out by the Request Owner?
This activity is carried out by the RO on a local level and by the Global Review Coordinator on a global level.

Why do we need to send new investigator information to IMPACT CoE?
To ensure the interface with ARGUS is activated for safety reporting.

Do we manage the IIT status with GEMS and stop using HORIZON/IMPACT?
Yes

Does the actual review of the publication happen in GEMS and not CLEAR®?
The Publication Review will continue to happen in CLEAR® with the outcome recorded in GEMS.

The new Global SOP states that after the integration of GEMS and Horizon, the Global Review Coordinator is responsible for triggering study creation from GEMS in Horizon. Is this correct?
Once the study receives global approval, GEMS will notify Horizon, the Horizon team will generate an NCC code, which is then automatically transferred into GEMS.

GEMS external portal / pre-submission

What are the benefits of GEMS for the Investigator?
- Easier submission of applications and can be done from any device
- The ability to manage the application process in one place
- Quicker review and approval of applications by Sandoz

If an investigator asks for support when submitting a request step-by-step e.g. in a virtual meeting, can we accept and help to submit it to GEMS?
In the first instance please direct the investigator to the [GEMS IIT External User Training Guide](#) or [GEMS IIT Video](#) . If more assistance is required, there is also a step-by-step PowerPoint guide for external users on how to submit a request in the external portal. Please contact the GEMS team for further information.

External Submissions

Is there a specific form for Investigator Qualifications and is the Investigator responsible for filling in his/her own qualification?
There is a specific section on Investigator Qualifications in the external portal, which the investigator is required to complete.

Do we have the same application process for Research Collaborations (RCs) via GEMS? If a proposal is submitted as an IIT, but later it becomes evident that it will be a Research Collaborations (RC), is it possible to change this in the system?
RC application is not currently available within GEMS. The submission can be withdrawn from GEMS and submitted as a new funding request via email (or according to the RC guidelines).

If an IIT request in GEMS requires additional information during the review process, how do we proceed?
There is a "Return to Applicant" function, which allows additional information to be provided by the Investigator during the review process. However, this does not apply to the original request submission. Once the request is submitted, the information is 'locked' and cannot be changed.

If there is an IIT request that comes via email and we know we will not be able to support it, does the HCP still need to enter it into the GEMS and get it rejected through the system?
Every request should come via GEMS, however if you have already informed a physician outside the system that the proposal will not be supported, then it does not have to be entered into GEMS for a rejection.

If the sponsor does everything on behalf of the Investigator, can we have the sponsor as the main point of contact?
The main point of contact is always the Investigator.

What is the timeline from submission to approval of concept?
There is no fixed timeline. It varies according to the accuracy and relevance of the request, as well as the time taken in the review process.

Internal review and approval

Can the Global Review Coordinator (GRC) or other local medical representative see the request in GEMS when it is initially submitted?
The GRC can view the request once they have been assigned by the Request Owner.

Who completes the Fair Market Value (FMV) assessment for each country?
The RO completes the Requested Funding section. This is largely auto-completed with information supplied by the Investigator, but requires RO input on FMV and the final Sandoz Approved Amount. Any documentation to support FMV should be uploaded via Documents Upload.

Is there a list of communications which are and are not done automatically by GEMS?
All registration notifications, role assignments and impact reports are communicated automatically by GEMS. Some ad hoc, or more sensitive communications such as the rejection letter, are available as templates which should be customized prior to manual communication.

If we have to manually notify the GRC by email, will we get the list of global / regional people who are registered in GEMs?
There is a list of reviewers available within GEMS.

Is there a placeholder if no drug is in focus?
Please select 'Other' from the drop-down menu

If the PI wants to revise the concept sheet prior to completion of the Sandoz review/approval process, can the PI submit the revision?
Yes, however the PI has to formally inform the RO, at which point through the "Return to Applicant" process the original concept sheet can be withdrawn from the review process and the revised document can be submitted (the original concept sheet will still remain in GEMS as part of the initial submission).

Can the local concept submission review be done prior to the PI submitting it via GEMS?
All activity around the submission of a concept must take place within GEMS.

If the submission is rejected, who is responsible for sending the notification sent to the Investigator?
The Request Owner will provide the rejection notification via the GEMS portal.

In case of a change in planned dates, do these need to go for re-approval?
No.

Does GEMS integrate with the finance system to trigger milestone payments or does this happen independently?
GEMS is integrated with SAP. Payments will be generated outside of GEMS but will be triggered by data entered into GEMS. This includes milestone payments.

Will there be 'templates for minutes' in GEMS?
Currently there are no templates in GEMS however you can upload the local minutes following a review / meeting.

Who is responsible for PO creation?
The Request Owner should request a Purchase order number or for manual entry from their local finance team.

Can planned dates be changed if the study is going very slowly?
Yes, planned dates can be changed.

Does the Investigator get an email requesting the completion/filling out of dates?
The Investigator receives email notifications as soon as an Impact Report is available for them to complete.

Does GEMS automatically send notifications/reminders for safety reconciliation reports?
Yes, these are automated and are dependent on the determined frequency safety reconciliation set by the Request Owner.

Will GEMS have an Audit Trail that will store all emails, documents etc.?
Yes, there is a full audit trail available for every submission.

Will the scope of the Redundancy Check include similar study concepts that run/have run outside Novartis?
No. The redundancy check focuses on data from GEMS IITs only

If the protocol is rejected, is there an option for protocol amendment and re-submission?
The investigator submits a draft protocol in the first instance. This is reviewed and if changes are required, they can be made at this point before the Final Protocol is submitted. If changes are required after the Final Protocol has been submitted and approved, the Investigator is required to complete a Protocol Amendment form.

Is the Start of data collection the planned date timeline stated on Protocol, or when the Investigator actually starts and finishes?
The Planned Date is entered into GEMS following notification by the Investigator. The Actual Date is when the Investigator has started the study. Both dates are required to be completed in GEMS.

Publication / TPSR approval

Do we store the protocol and the TPSR in eDMS?
No, these are all now stored in GEMS.

If a publication is rejected by a journal and the same article is then submitted to another journal, is any action required in CLEAR?
No.

Is there a due diligence request for publication available? It currently shows as 24 months post actual LPLV in the new SOP.
A publication due diligence impact report is triggered once the publication is overdue in line with the timeline stated in the SOP.

Are Investigator notifications also copied to the local RO/CMR?
The RO/CMR is not in cc of these notifications.

Is it possible to have an IIT that is cross-divisional?
We would need to look at this case by case; however we may have to identify one division as primary to manage this from Sandoz side