Procedure for Compassionate Use
Cross-Business
SOP_454971 (2.0)

Why do we have this SOP?

What does this SOP cover?

This procedure is the process for providing *Investigational Medicines* to patients for *compassionate use* (see POL_87186). This SOP applies to Pharma and Vaccines.

ⓘ Compassionate use can be for a population or group of patients or on an individual request (named patient) basis.

ⓘ The primary intent of compassionate use cannot be to address research questions. Where we have research questions, a human subject research study is considered.

Why should you read this?

If you are involved in the decisions for and development of compassionate use strategies, GSK compassionate use programmes derived from those strategies, identification and handling of compassionate use requests or the approval or supply of Investigational Medicines for compassionate use, then this SOP applies to you.

If you are a/the:

Development Lead (e.g. Early Development Lead (EDL), Vaccines Medical Development Lead (VDL), Medical Development Lead (MDL), Global Medical Affairs Lead (GMAL), you are accountable for the compassionate use strategy for specific investigational medicines and for designating programme leads (the Programme Lead can also be the Development Lead).

Programme Lead (e.g. Project Physician Lead (PPL), Clinical Investigation Leader (CIL), you are accountable for the implementation of the GSK Compassionate Use Programme for a specific investigational medicine.

Chief Medical Officer (CMO) or Business Unit CMO, you are accountable for approving the compassionate use strategy and any requests that are outside this strategy.

Country Medical Director (CMD) you are accountable for ensuring Local Operating Company (LOC) support for the Programme Lead. This includes forwarding requests for GSK consideration, interactions with local *Healthcare Professionals* (HCPs) and ensuring local regulatory requirements are met.

What do you need to do?

Key: ✪Critical action ⓘHelpful tip

How do you do it?

✪ Compassionate Use related documentation is stored in a validated repository overseen by the programme lead.

ⓘ Additional information and resources may be found at:
https://myconnect.gsk.com/sites/ocmo/Global-Medical-Governance/Pages/Compassionate_Use.aspx

1 Strategy and Programme Set Up

For every GSK investigational medicine (excluding Consumer Healthcare Products), **Development Lead** considers the future need to provide the medicine through compassionate use.

The need (or not) for a compassionate use strategy is agreed with the CMO and documented. All medicines considered for a Commit to Medicine Development (C2MD) milestone include a recommendation to develop a strategy for compassionate use (or not).

ⓘ If you are responsible for a medicine in development post C2MD, where a decision to develop a compassionate use strategy has not been taken, consider the need for a compassionate use strategy. Where a need is identified, seek CMO agreement and follow the steps described here for the creation of a strategy.

CMO agreement for a compassionate Use strategy initiates the next steps.

Development Lead identifies and designates individuals required to create and develop the compassionate use strategy. Individuals representing Medical, Clinical Supply, Regulatory and Legal are included.

The strategy includes compassionate use criteria, timing, indications, regulatory, supply considerations and the proposed Programme Lead. The strategy includes the role of a Compassionate Use Programme and/or Individual Requests as applicable.

In general, a Compassionate Use Programme, where the medicine is provided to a group or population of patients meeting specific criteria, is considered the method of choice.

Where this is not considered appropriate (e.g. for logistical or legal reasons) Individual Requests for specific patients are considered.

ⓘ Compassionate use programme: This is a mechanism for providing compassionate use supported by the provision of a GSK treatment protocol. This provides detailed information for administration of the medicine, safety monitoring and minimum pharmacovigilance reporting responsibilities

For GSK compassionate use programmes, GSK supports regulatory submissions and provides information to HCPs which is presented as a treatment protocol.

ⓘ For Individual Requests, the requesting HCP (and CMD where applicable) ensure appropriate regulatory submissions are made in line with local laws and regulations. GSK provides information to help ensure the medicine is used appropriately.

CMO reviews proposed strategy and advises the Development Lead on any recommendations. **CMO** provides final approval.

Development Lead develops an Implementation Plan for the strategy.

ⓘ Implementation plan: This outlines how the strategy is implemented. This may include the detail for provision of a compassionate use programme, or supply on an Individual Patient basis and is approved by the **Development Lead**.

✪ Implementation plan includes criteria to guide considerations for patient suitability (e.g. absolute contraindications).

Development Lead assigns Programme Lead for GSK compassionate use programme.

Programme Lead is accountable for generating eTrack IDs' in accordance with business rules and ensures all relevant systems are updated.

Programme Lead oversees the development and finalisation of Treatment protocol that is supplied in conjunction with the compassionate use medicine. Where an Individual Patient Request is considered, an information pack is prepared which clarifies minimum requirements for medicine administration, safety monitoring and safety reporting.

Project Physician Lead approves the Treatment Protocol or Information pack.

ⓘ For the Treatment Protocol, consider utilising respective business unit (study protocol) approval process where appropriate.

CMD of countries where demand is anticipated is accountable for identifying any local requirements or constraints and communicating this to the Programme Lead. E.g. regulatory, legal, supply and sanctions.

Supply Chain Manager confirms demand/supply plan incorporating any changes required to update the implementation plan.

Development Lead ensures there is a mechanism to manage requests for a particular medicine.

Programme Lead is accountable for posting information about compassionate use access to the external facing GSK website. Local regulations must be considered.

At this point, the GSK compassionate use programme is established and ready to manage a request.

2 Request Received

✪ **Development Lead** undertakes action when no Programme Lead assigned.

Programme Lead receives request.

ⓘ CMD is notified if not already aware.

All requests

Programme Lead determines if the patient(s) detailed in the request may be suitable for a clinical trial. Where this is the case, Programme Lead connects the requestor with the clinical trial team and informs CMD.

ⓘ Personally identifiable patient information (e.g. names) is not collected or shared between the Programme Lead and the Clinical Trial team. If such information is received it is handled according to SOP_87131.

If not eligible for a clinical trial, **Programme Lead** establishes if an approved GSK compassionate use strategy exists to support the request. If so, the request is managed according to that strategy.

Programme Lead establishes if an approved GSK compassionate use programme exists to support the request. If so, the request is managed according to the GSK compassionate use programme. Go to step 3 'Decision to Approve or Reject'. These are referred to as Programme Requests.
Where the compassionate use request is on strategy but a compassionate use programme is not appropriate the medicine may be supplied on an Individual Request basis.

For Individual Requests:

Programme Lead reviews the request and treatment plan supplied by the HCP.

Programme Lead ensures the minimum requirements for the treatment plans are in place (and seeks further information from the HCP to complete the plan if needed).

Programme Lead informs HCP that approval requires evidence that local regulatory requirements are met and that the treatment plan incorporates appropriate safety monitoring and reporting requirements. The timing of the approval decision depends on confirmation of the above.

ⓘ External HCP and CMD where required, are accountable for fulfilling local legal and regulatory requirements and for achieving regulatory submission for Individual Requests.

Supply Chain Manager reviews supplied treatment plan and develops Demand / Supply Plan.

If the request is not covered by the approved compassionate use strategy, **Development Lead** considers whether it may be appropriate to expand the strategy or initiate a new strategy.

Where this is the case, **Development Lead** seeks CMO approval to develop or modify the strategy.

ⓘ In an emergency this can be done by contacting the CMO directly according to business practice (e.g. through a direct conversation, by telephone).

Where the strategy update is approved, it is documented and the supply of the medicine can be considered for a decision to approve (see step 3).

Development Lead undertakes relevant step 1 'Strategy and Programme Set up' activities to update the strategy. In an emergency, this does not need to be completed prior to supplying the medicine.

If it is clear at this stage that GSK is unable to support the compassionate use request, the **Programme Lead** ensures that requestor is informed that request will not be progressed.

Programme Lead and **Development Lead** keeps CMDs updated and proceed to Step 3 'Decision to Approve or Reject'.

3 Decision to Approve or Reject

✪ Programme and Development Lead can only approve requests if they are themselves a physician. If the Program or Development Lead is not a physician a named GSK physician must provide additional approval.

ⓘ **Development Lead** is accountable for ensuring that approval decisions are adequately informed by a suitably qualified named physician.

Programme Requests: For GSK programmes (groups or populations of patients)

Programme Lead in consultation with regulatory and CMD as required, assesses the compassionate request against:

- Criteria in the Implementation Plan
- Assurances that local regulatory requirements are or will be met. This must be in place prior to approval.

Programme Lead approves or declines request.

Individual Requests

Programme Lead in consultation with regulatory, safety and CMD as required, assesses the compassionate request against:

- Treatment Plan supplied by the HCP

✪ Key considerations include but are not limited to confirming that the request is consistent with GSK's view for the most appropriate use of the drug and that appropriate Pharmacovigilance is in place.

- Assurances that Local Regulatory requirements are or will be met. This must be in place prior to approval.

ⓘ In circumstances where GSK submits documentation for regulatory authority approval, any statements related to the suitability of the medicine for an individual patient are made under the accountability of the treating physician.

✪ Suitable information to support supply of the medicine must be provided.

Programme Lead approves or declines request.

For approved requests:

Programme Lead informs the requestor (and relevant team members) when requests are approved or denied.

Programme Lead instructs team members (e.g. Regulatory) to enter the approval status of Compassionate use Programmes onto OPAL and all other requests onto appropriate validated systems (eTrack ID/s) in accordance with Business rules and ensures all relevant systems are updated.

ⓘ **Programme Lead** ensures that requests which are declined are stored in the validated repository with the rationale for the decision.

4 Supply Medicine

Programme Lead notifies Supply that a request is approved.

Supply initiate the supply process, preparing (label is approved according to relevant creation and approval processes) and releasing supplies according to internal

procedures.

ⓘ Please refer to SOP_53198 for Pharma and SOP 9000000513 for Vaccines.

Programme Lead (Pharma) **/ Clinical Trial Supply Manager** (Vaccines) allocate appropriate released supplies to the request and create the shipment order.

ⓘ Programme Lead is given access to tracking and shipping information (Not Applicable for Vaccines). **Supply** ship compassionate use medicine to HCP for administration to patient according to internal procedures.

5 Programme Maintenance and Re-supply Requests

Programme Lead re-assesses strategy at least once per year (or sooner if information emerges that changes the benefit:risk assessment or impacts the operational plan) in consultation with development lead, supply and regulatory to decide if modifications are required. **CMO** is informed of and approves any significant changes from the previously approved strategy. Changes are implemented through the process described in step 1 Programme Setup.

Programme or **Development Lead** is responsible for ensuring that HCPs managing patients in receipt of GSK compassionate use investigational medicines have the latest information (e.g. updated treatment protocol, GSK information pack and externally posted information).

When it is decided that a specific GSK compassionate use programme is no longer supported, **Programme Lead** constructs and implements a shut down plan in consultation with the programme team including Legal. This incorporates consideration of the ongoing patient need in the programmes absence and notification of regulatory authorities where required.

ⓘThe same shut down plan considerations apply when it is decided that non-programme requests will no longer be approved.

Programme Lead monitors and communicates other changes such as increases or decreases in demand to Programme Team on a needs basis.

Programme Lead reviews, approves or rejects re-supply requests in conjunction with the implementation plan.

Training & Communication

All staff in scope of this SOP are expected to review POL_87186 and this supporting Compassionate Use SOP and then complete the Read and Understand Module assigned to each document. These modules ask staff in scope to certify that they have read and do understand the policy and supporting process associated with compassionate Use programmes at GSK.

Please visit compassionate use web area for supplementary information:
https://myconnect.gsk.com/sites/ocmo/Global-Medical-Governance/Pages/Compassionate_Use.aspx

Monitoring

Management assess and monitor controls to ensure they are in place, in use and effective. In addition, Business Units and Global Support Functions management are accountable for establishing a level of Independent Business Monitoring to verify controls are sufficient and sustained to manage the risks associated with their business activities.

If you have concerns

If you have concerns about how to apply this SOP bring them to the attention of your manager and/or raise them through the Medical Governance Framework (see POL_87166). If you are aware of violations of this company procedure, please report them to Compliance or through Speak Up channels.

To find your local Speak Up integrity line number or to report online, please visit: www.gsk.com/speakup

If you are out of compliance or feel you are unable to comply with the procedure please contact your business unit Compliance Officer

Definitions of terms in italics in this document can be found in the *GSK Written Standards Glossary*

Administration

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