

INVESTIGATOR INITIATED TRIALS

The GW Charter

GW's Definition of an Investigator Initiated Study

"A clinical or non-clinical study with scientific or medical merit developed and sponsored by an independent investigator or academic sponsor. Such a study may be conducted without the participation of GW, but is a study for which the IIT sponsor has requested and GW has agreed to provide drug product, funding and/or other contribution to the conduct of the study".

Note: for the purposes of this Charter, the words 'trial' and 'study' may be taken to mean the same.

Introduction

GW is committed to delivering innovative therapies, based on our cannabinoid platform, to patients with substantial unmet needs worldwide. As part of this commitment, GW believes that independent research activities conducted by qualified investigators plays a key role in shaping and complementing GW-sponsored research and helping ensure that we learn more about the therapeutic opportunities and benefit/risk profile of our products. Such investigator-led research must set out to address appropriate scientific and/or clinical objectives supported by valid study designs in which the rights and protection of patients, and the utility of the data collected are of paramount importance.

To this end, GW therefore supports the concept of investigator-initiated studies using our materials. These studies may be clinical studies or non-clinical studies and may be focused on researching a drug or disease state. This support may involve funding, and is underpinned by rigorous processes and an appropriate governance structure.

Support

GW may supply drug product (including placebo), funding or other services to support an IIT, subject to a formal agreement which requires that investigator or other academic sponsors comply with applicable local laws, rules, guidelines and regulations.

There are several key principles which underlie the support that GW may offer to such studies:

- The scientific/medical question being addressed by the study must be a valid and new question, ensuring that any data generated by an IIT complement the existing body of evidence and not simply repeat research that has already been done.
- The design of the proposed study must be consistent with all regulatory and ethical principles and guidelines.
- The design of the proposed study does not put patient safety at risk.
- An investigator/sponsor must undertake to disseminate the results of the study in a way that is timely, transparent and appropriate.

The conduct of an IIT is independent of GW. The investigator or affiliated study sponsor has responsibility for study conception, design, operational execution, data handling, data

analysis/interpretation, subsequent reporting/ publication, and ensuring compliance with all local laws and regulations.

Guidelines

GW has developed the following guidelines that shape our approach to IITs:

1. The investigator and the proposed site(s) of investigation must be capable of conducting research under Good Clinical Practices (and/or other GxPs where applicable). In study sites where GW is not satisfied that the relevant GxP standards exist, we will not support IITs.
2. GW has developed and will maintain robust medical and scientific governance systems in place at all levels of the organisation. Under no circumstances will GW permit the involvement of sales and marketing associates in any aspect of IIT design, review and approval, operational execution, funding or transfer of value to a sponsor/investigator undertaking an IIT. In this way, the decision-making process around the support of IITs will be wholly independent of any commercial considerations.
3. The review/approval process focuses specific attention on ensuring that patient safety is of paramount importance in the proposed IIT.
4. GW will establish a training program that ensures that all GW staff are aware of the policies and practices that ensure that GW support for IITs is based on rigorous compliance with all relevant laws and guidelines, and that no undue GW influence is brought to bear on the investigator/sponsor.
5. There must be complete financial transparency on any transfer of value or provision of funds provided to any investigator or institution worldwide undertaking an IIT as part of a contractual agreement with GW.
6. GW will tracking and monitor our IIT-contracted obligations and practices and share appropriate data with key stakeholders.

Identification of appropriate Investigator Sponsors.

Before approval of any proposed IIT, GW will ensure that the investigator is able to meet all requirements of all relevant GxPs. For clinical IITs, this means GW will ensure that the investigator is able to meet all requirements of Good Clinical Practices, as defined in relevant ICH guidelines, and all ethical practices as identified by the Declaration of Helsinki. For non-clinical IITs, this means GW will ensure that the investigator is able to meet all requirements of Good Laboratory Practices or other relevant quality standards applicable to the proposed study. Any animal studies proposed must only be conducted in facilities that have the appropriate government licenses required for ethical animal research. GW will not provide training to sites which are not already capable of operating under GxP with a view to establishing GxP compliance at the site.

For clinical IITs, there are certain documentary requirements that allow for GW to be assured that the appropriate quality standards are in place at the potential investigational sites. IITs will not be authorised until the Investigator has supplied the required documentation. These are specified within the relevant SOP (CL-PL-006-V6). Briefly they are:

- Recent evidence (within previous 3 years) of the potential investigator and site personnel being trained in GCP (e.g. a signed attestation by the potential investigator of having completed GCP training).

- Recent evidence (within previous 3 years) of the potential investigators experience in undertaking clinical research e.g., documentation from a Local Ethical Committee/Institutional Review Board confirming previous participation in clinical research, or documented proof of involvement in a previous clinical trial.
- Evidence of a current license to practice medicine and good medical standing (including no evidence of restrictions by a regulatory/government authority to undertake clinical research).
- GW staff will ensure the validity of all of the above requirements as well as those requirements stipulated in SOP CL-PL-006-V6 used in the conduct of IITs.

Governance

GW may communicate to the scientific and clinical world those areas of research interest to the company. However, under no circumstances will GW solicit a request for an IIT. The following principles apply without reservation to the IIT process.

GW must not direct the scope, objective, design, and operational conduct of any IITs. GW may provide comments to ensure that the study is based on sound scientific hypotheses, and protects the safety of subjects in terms of dosing, schedule and potential interactions of approved or novel drugs in combination studies.

- There will be no marketing and sales influence (actual or perceived) on the selection of an investigator, on the choice to support his/her IIT, nor on any aspect of IIT design or execution.
- All IIT funding will be initiated and controlled via the medical departments within GW, with financial oversight. GW support to the study is limited to coverage of financial expenses and/or with the supply of GW products, without exceeding fair market value.
- Based on scientific merit and request by the IIT investigator, GW may consider on a case-by-case basis additional support (e.g., statistical design expertise, case record form design etc.).
- The investigator takes full responsibility for the design, initiation, management, data analysis and reporting of the study (including local regulatory obligations).

GW's IIT process is defined within its SOPs, but can be summarised briefly as follows

1. GW receives an unsolicited request for an IIT using a GW product on the designated application form, accompanied by the CV of the investigator.
2. The proposal is then evaluated by the IIT Committee within GW, acting within all GW guidelines and SOPs, and based on the following principles:
 - Maintaining independence of the investigator and their study concept
 - Good ethical and medical principles
 - Sound scientific design and methodology
 - Investigator's qualifications and expertise
 - Ensuring that the IIT proposal is aligned with the GW strategic scope for that therapeutic product

The research proposal and provision of financial and other support between GW and the institution and/or investigator must be appropriately documented in an agreement that defines roles and responsibilities. The agreed financial support is linked with defined milestones such as patient recruitment and completion of the final study report and shall only be paid if these milestones are achieved.

The progress and results of the IIT will be collected, analysed, and adequately reported to GW by the investigator, including, at a minimum, submission of periodic progress, final study report and safety information.

Financial Principles and Data Transparency

GW is committed to both data and financial transparency. We believe that sharing information in all areas of research, without compromising patient data or confidentiality, supports sustainable innovation and accountability. Therefore, when GW provides direct or indirect financial support to a third-party sponsor (e.g., investigators or research institutions) we believe that the scientific community and patients have a right to access information about the types of IITs that we support

This means that in GW we track all value transfers provided to an investigator or an institution and ensure that our interactions are properly documented in a written contract. We also encourage institutions and investigators that benefit from GW research support to publicly share appropriate research results. All signed IIT agreements across the world are filed in the centralized GW Global Contract Repository.

Training Principles

GW will ensure that all relevant GW staff are regularly trained in the principles underlying IITs, in order that those principles outlined in this Charter are understood. All training will be documented and all employees involved in the administration of IITs will sign that they have read and understood the IIT principles and governance structures.

Tracking and Monitoring

GW will ensure the compliance of investigator/sponsor IITs by regular monitoring and tracking of their performance against target, and by targeted audits of investigator/sponsors, so that site compliance with GXP and ethical considerations will be assured.