Clinical Safety and Pharmacovigilance (PV)

As the Sponsor of a ViiV Healthcare (VH) Supported Study, you (not VH) will be primarily responsible for all study activities, including: submission of all safety reports to all concerned parties, including reporting to concerned regulatory authorities; and medical governance for the study (i.e., welfare of the study population), in accordance with ICH Good Clinical Practice (GCP) all local regulations and legal requirements applicable to the study. This will be reflected in the terms and conditions of the contract between you, as the Sponsor of the study, and VH, should VH agree to support the proposed study.

As development product owner and/or Marketing Authorisation Holder (MAH), VH has a responsibility to collect and analyse safety information on its Medicinal Products. This is in order that the company can fully understand the risk-benefit profiles for its products, and can provide accurate safety information to: participating Investigators and subjects; ethics committees, regulatory authorities; and prescribing physicians and their patients.
Should VH agree to support the proposed study, you and your investigators will play an important role in working with VH to monitor safety and help manage risks related to any VH study medication(s).

Safety Data Exchange: Depending on study design and involvement of any VH study medication(s), at minimum Sponsors are requested to report to VH the following safety information within pre-specified timeframes:

- Serious adverse events (SAEs) and pregnancy reports for subjects exposed to VH medications during the course of the study. If you intend to use your own case report form (CRF) pages to provide these to VH, then blank copies of these CRF pages will be requested to determine if they contain all the necessary data fields to meet ICH GCP and regulatory requirements. Alternatively VH SAE and/or pregnancy CRF pages can be provided for you to use.

- Medical device incidents (associated with an SAE, or a non-serious AE, or a product complaint/simple malfunction not associated with either an AE or SAE) experienced by subjects exposed to VH medications categorised as medical device, or non-study participants (e.g. caregiver, site staff or bystanders) involved in the administration of a medical device to deliver the VH medications. If you intend to use your own Medical device incident pages to provide these to VH, then blank copies of these pages will be requested to determine if they contain all the necessary data fields to meet ICH GCP and regulatory requirements. Alternatively VH Device incident reporting can be provided for you to use.

- Targeted information on AEs of Special Interest (AESI) for certain VH study medication(s) (specific VH AESI CRF pages will be provided for you to consider using in your study)

- Any other significant safety issues relating to the VH study medication(s) (e.g., circumstance leading to a Protocol amendment for purposes of subject safety; results that indicate a trend in safety data; an adverse effect or an apparent lack of efficacy that may alter the risk benefit profile; threatened or pending action by any authority responsible for granting approvals or registrations; safety or efficacy related regulatory authority enquires).

For blinded studies, provisions will be negotiated for the prospective reporting to VH of individual case safety reports (ICSRs) that Sponsors have unblinded to fulfil their obligations for: individual

subject management; and/or any regulatory requirements for expediting unblinded ICSRs to concerned parties during the course of the study.

Should the proposed study involve a data monitoring committee, advanced notification of review meetings will be requested by VH, as well as receipt of any safety related recommendations, findings and other pre-specified outputs from these meetings.

These details will be mutually agreed in the contract between you and VH, should VH agree to support the proposed study. Reporting the above outlined information to VH does not relieve you from your regulatory reporting responsibilities as study Sponsor.

Risk Mitigation and Management: For interventional studies, standard VH guidance on risk management and monitoring language have been developed for Supported Study protocols utilising VH medications. These guidance documents are based on the current key risks associated with the use of the VH medications, and include specific risk mitigation strategies (e.g., subject entry criteria, withdrawal criteria, monitoring strategies and toxicity management guidelines) to help minimise and manage these risks. Should VH agree to support the proposed study, you will be requested to consider this guidance when writing the study protocol.

Date last updated: 30 November 2022