ALEXION CLINICAL TRIALS DISCLOSURE AND TRANSPARENCY POLICY

PURPOSE

This policy describes Alexion's position on Clinical Trial (CT) transparency, disclosure, and data sharing activities related to Alexion-sponsored research and clinical programs. The intent of this policy is to enable compliance with all applicable laws, guidelines, and standards, and to protect patient privacy as described in applicable regulations. It also serves to demonstrate Alexion's philosophy of dedication to patients as shown by CT transparency in the area of rare diseases and highly specialized conditions. All activities associated with this policy are meant for informational purposes only and are not intended to promote any product or use.

As part of this policy Alexion will:

- Assure that research practices are transparent, responsible, and compliant with applicable laws, regulations and guidelines.
- Commit to the PhRMA/EFPIA, EUPATI, and IFPMA Principles for Responsible Clinical Trial Data Sharing.
- Assure protection of patient privacy, publication rights, and proprietary information, while honoring this commitment

This policy is written in accordance with CT transparency regulations, standards and principles for responsible CT data sharing.

SCOPE

This policy applies to the following:

- CT registrations and results disclosure of Alexion-sponsored studies on externally facing public websites (eg, ClinicalTrials.gov, EUCTR, EnCePP/EU PAS, clinicaltrialsregister.eu, and the Alexion clinical trials website, www.alexionclinicaltrials.com).
- CT data, ensuring patient privacy by de-identification
- CT document sharing as presented in pseudonymized clinical study reports (CSR), including CSR synopses, as well as plain language summaries (PLS) for CSRs and publications that are developed by or in collaboration with Alexion.

This policy will apply to all Alexion personnel (including service providers to whom Alexion has delegated tasks) and external contributors involved in CT registration, results posting and data/document sharing.

POLICY

This policy describes CT data sharing activities relating to Alexion-sponsored studies supporting disease indications that have received Health Authority approval including study registration, study results, report or summary document pseudonymization, plain language aggregate summaries, and data sharing.

1. Public Access to Clinical Trial Information

CT Registration

Since January 2005, Alexion has registered all applicable Alexion-sponsored interventional CTs on clinical trial registry sites such as Clinicaltrials.gov and EUCTR.

Alexion will register all applicable clinical trials on clinical trial registry sites as required by law and/or regulation, and in accordance with local requirements and applicable industry guidance.

Alexion will register applicable clinical trials prior to the first patient being consented for the study, aligned with the International Committee of Medical Journal Editors (ICMJE) guidelines.

Alexion will also register certain non-interventional studies on the EU PAS Register before the start of data collection as per local regulations.

CT Results Disclosure

Since January 2005, Alexion has posted study results for all applicable Alexion-sponsored interventional CTs on clinical trial registry sites such as Clinicaltrials.gov and EUCTR. Beginning in August 2018, Alexion has also posted redacted protocols and statistical analysis plans on ClinicalTrials.gov concurrent with disclosure of trial results.

Alexion will publicly disclose summary study results of all Alexion- sponsored interventional CTs conducted in patients and/or healthy participants (regardless of study outcome, where the study is conducted, approval status of the product, and unapproved uses of approved treatments) on all sites where the study was registered as required by law and/or regulation.

CT results from Alexion-sponsored interventional studies will be disclosed on ClinicalTrials.gov as per the FDA Amendment Act. Alexion will continue to post results of all Alexion-sponsored studies on EUCTR in accordance with the timing and modality set forth by the EMA. Results from the following will be posted in accordance with mandated timelines.

- All studies registered on Clinicaltrials.gov with primary completion dates on or after 18 January 2017
- Phase 1 to 4 interventional studies registered on the EUCTR. As per the EUCTR practices, Phase 1 study results are posted but usually are not visible to the public.
- Non-interventional studies registered on the EU PAS Register

CT results as reported on the above sites will also be posted on the Alexion Clinical Trials website (www.alexionclinicaltrials.com) in addition to redacted synopses of CSRs for studies that completed after 01 Jan 2015.

Clinical Study Reports (CSRs) and Clinical Summary Module Disclosure

Alexion is committed to protecting patient privacy. Redacted and psuedonymized CSRs for EU clinical trials on products covered in a clinical trial application and that have been approved in the EU will be accessible on the EMA Clinical Data Website. To the extent possible, Alexion also intends to provide the anonymized versions or, to the extent anonymization is not feasible, pseudonymized versions of the CSR body, protocol and protocol amendments, sample case report forms, and

documentation of statistical methods for all studies done by or on behalf of Alexion on the Alexion clinical trials site, in accordance with applicable laws and regulations, as described below in section

Alexion will also provide redacted synopses of all CSRs for interventional studies that were completed after January 2017 on the Alexion clinical trials website.

Scientific Publication of CT Results

Alexion will make best efforts to ensure that all Alexion-supported research manuscripts for publication are or will be submitted within 18 months after the completion of clinical trials for marketed products (regardless of the outcome of the clinical trial) to peer-reviewed, indexed medical or scientific journals that are visible to the public via Open Access. This commitment also pertains to investigational medicines whose development programs have been discontinued.

Sharing Clinical Trial Results with Study Participants and Public

Alexion is committed to sharing aggregate summary results of clinical trials with the general public, including trial participants. In preparation for new requirements under the EU Clinical Trial Regulation, Alexion is in the process of ensuring that summarized study results for clinical studies that completed on or after 01 January 2015 are available in plain language, with limitations as described below in Section 2. Alexion will continue development of summarized study results in plain language for certain studies over a pilot period and will voluntarily expand current disclosure standards, laws and regulations by making them available not only to study participants, but also to the general public via the Alexion Clinical Trials website.

2. Sharing Patient-Level Data (PLD)

In support of our mission to support patients and families affected by rare diseases, Alexion allows researchers to request access to PLD from Alexion-sponsored clinical trials that have been de-identified, pseudonymized, or anonymized, as required by applicable law. Prior to disclosing PLD, Alexion will ensure that patients have provided informed consent to share their PLD with the requestor(s). Providing qualified academic researchers access to clinical study data may help advance medical science or facilitate creation of further knowledge and understanding to discover and develop life-changing treatments for rare diseases.

In January 2019, Alexion began accepting requests for access to clinical study data (regardless of study outcome or where the study is conducted). Researchers can request access to PLD from Alexion clinical studies and publications for compounds and indications approved in the United States and the European Union on or after January 1, 2015, following a defined process that is initiated by submission of a formal data request and other supportive information. All research proposals must be submitted by completing a Data Request Form (access at www.alexionclinicaltrials.com). Considering the need to allow enough time for publication of results as well as consideration of other factors listed below, approved requests for PLD will be made available via a controlled access portal within a reasonable time following regulatory approval of submissions.

As data will be from CTs involving patients with rare diseases, Alexion will continue to protect patient privacy by sharing only PLD that have been de-identified, pseudonymized, or anonymized, as required by applicable law, has received informed consent from the patient allowing PLD to be shared, and for which there is not a reasonable likelihood that patients can be re-identified.

Data Request Review:

Once a request is received, an internal cross-functional team will review each request to ensure alignment with the scope of the policy and completeness of the request as well as check current or expected availability of the data set. Following validation of the request, an internal Steering Committee made up of subject matter experts, which includes representatives from Legal, Privacy, Statistics,

Medical, and Compliance and chaired by the Alexion Chief Medical Officer, will review the eligibility of the proposed research against the criteria below and render a decision. In cases where the validity of the researcher or proposed request is in question, Alexion will defer the request to an external Independent Review Team (IRT), for an objective opinion. The IRT membership comprises non-Alexion healthcare professionals and clinical biostatisticians and its membership will be recorded on the Alexion Clinical Trials website. Consistent with the Data Sharing Agreement, the Alexion Clinical Trial Data Sharing Steering Committee will review the decision by the IRT to inform the final decision on allowing access to data to enable protection of patient privacy, confidential information, and intellectual property rights.

Alexion will review data requests based on, at minimum, the following criteria:

- The scientific rationale and relevance of the proposed research to the advancement of science, medical knowledge, or patient care
- How the proposed research plan (including its design, methods, and analysis) will meet the scientific objectives
- The resources of the research team to carry out its research plan and meet these scientific objectives
- The plan to publish results of the research
- The real or potential conflicts of interest that may impact the planning, conduct or interpretation of the research, and proposals to manage these conflicts of interest
- Any real or potential competitive risks, including risks to intellectual property
- The qualifications and experience of the research team to conduct the proposed research
- The protection of patient privacy, to the extent applicable, and assurances not to re-identify any data that has been coded, redacted, de-identified or pseudonymized

Alexion will make available data from eligible studies after publication of the primary manuscript set forth in Alexion's publication plan. If a research proposal competes with a publication that is part of the publication plan developed for a study, Alexion will decline the research proposal, inform the researcher, and prioritize the planned analysis and publication.

If a research proposal competes with a planned/post-hoc analysis, Alexion will inform the researcher. If the planned internal analysis has not been reached within a reasonable time limit (not to exceed 12 months), the researcher will be informed of status, and/or decision to move forward with the analysis.

All researchers will be informed of the decision for data sharing. For approved requests, the researchers will sign a Data Sharing Agreement and will be provided access to the approved data on secure data sharing site.

PLD Sharing Limitations

There are circumstances under which Alexion may not be able to disclose data or where Alexion believes that the risks of sharing data outweigh the benefit of sharing it.

Circumstances that might prevent Alexion from sharing data include:

- Requests for CT PLD when the PLD cannot be reasonably de-identified or pseudonymized
- The study participants did not provide consent to permit Alexion to share the PLD with the requestor(s).
- The CT has not been sponsored by Alexion.

- The CT was conducted in healthy volunteers
- The PLD is part of a research collaboration.
- Providing PLD as part of an out-licensing agreement
- Requests from external clinical study investigators to access PLD from Alexion-sponsored clinical study or studies in which they have not participated
- Requests from research participants to access their PLD from a human subject research study
- Requests for PLD from journals as part of the peer review process
- There are legal or regulatory rules, guidelines or standards, or contractual or consent provisions that prohibit, or do not permit, disclosure of the data
- The recipient of the PLD will not agree to limitations on use and disclosure of the PLD set forth in the Data Sharing Agreement