ALEXION
AstraZeneca Rare Disease

Alexion Externally Sponsored Research (ESR): A Guide for Investigators

Introduction

At Alexion we are dedicated to making a meaningful impact for people living with rare diseases; our goal is to transform their reality for the better. Alexion recognizes the important role that Externally Sponsored Research (ESR) can play in complementing our company sponsored research to expand medical and scientific knowledge on rare diseases and our medicines.

ESR is defined as a study with scientific and medical merit that is initiated and managed by an external investigator ('sponsor'). The external sponsor assumes the legal and regulatory responsibility for the conduct and management of the research as defined by applicable local laws and regulations.

Alexion supports Externally Sponsored Research in two forms.

Investigator Sponsored Research (ISR): an unsolicited research proposal from an external investigator, conducted independently of Alexion.

Externally Sponsored Collaborations (ESC): may either be solicited by Alexion *or* proposed by an external investigator. The investigator and Alexion can collaborate on the study design and interpretation of the results.

The purpose of this guide is to provide a description of the requirements that must be met for Alexion to support any ESR proposal, the ESR submission process, and to highlight your obligations as the study sponsor. Please note that submission of an ESR proposal does not imply or guarantee approval.

Eligibility

The Alexion ESR program is open to all qualified investigators interested in conducting research in areas of mutual interest to Alexion. The external sponsor assumes all legal and regulatory responsibilities for the study.

Study Criteria

Submitted studies will be reviewed by a multi-disciplinary research committee, subject to passing a quality check. The proposed study should answer a legitimate scientific research question and will be assessed against, but not limited to, the following criteria:

- Consistency with Alexion's research areas of interest

- Importance and validity of unmet medical need or scientific question
- Rigor and quality of study design
- Likelihood of achieving its set forth objectives
- Qualifications and experience of the principal investigator to perform the proposed study

Types of Support

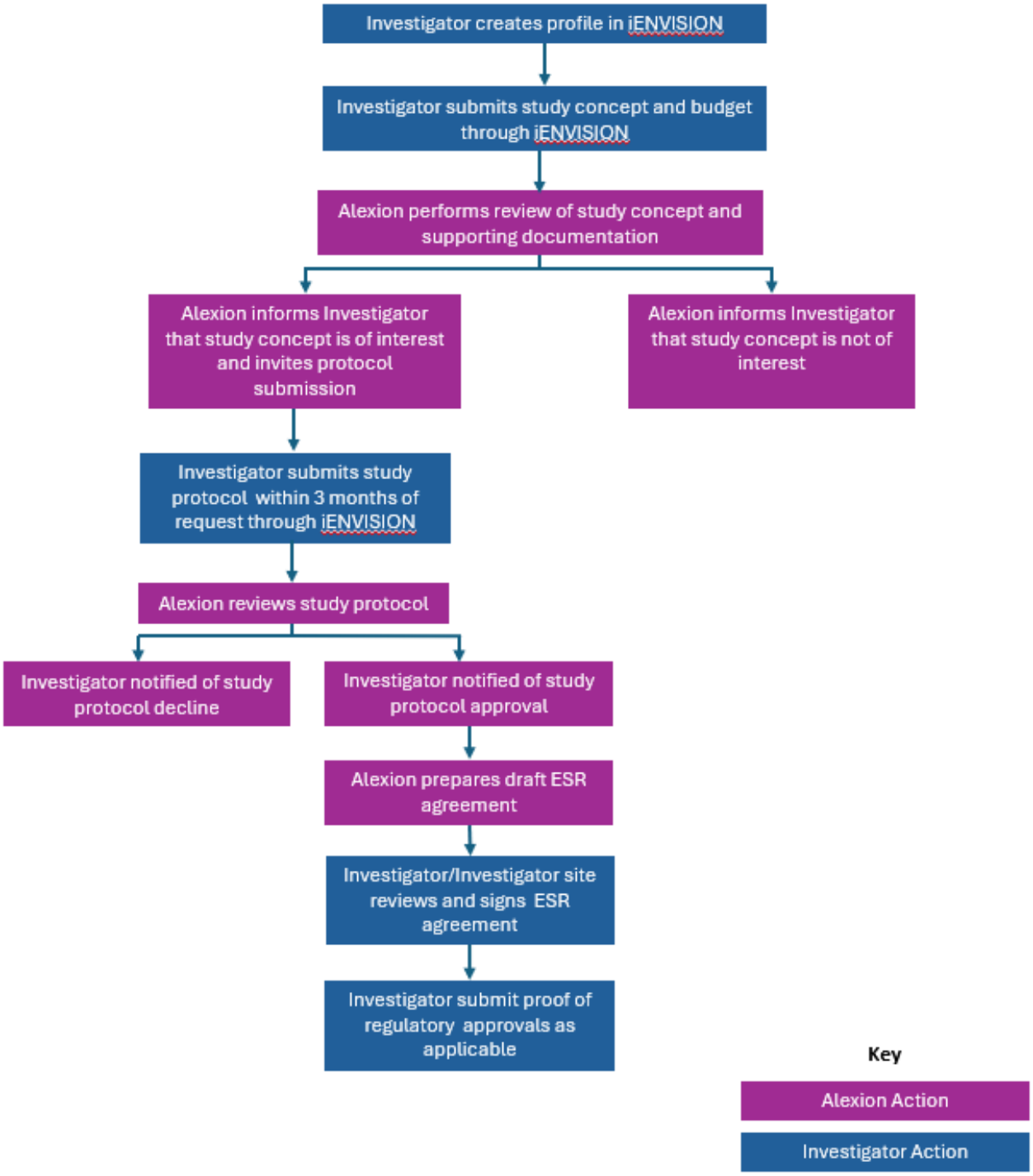
Both financial support and/or Alexion product can be requested in support of an ESR study. Alexion funds research at fair market value and all proposed study budgets will be subject to an assessment.
Alexion will only fund services that can be reasonably expected in the undertaking of a study, including but not limited to procedural costs (excluding those undertaken as part of routine operating procedures or standard clinical care), research personnel costs, outsourced vendor costs and publication fees.
Congress attendance and travel costs, student fees, capital expenditure (including equipment), and funding for research that has already occurred, will not be supported under the Alexion ESR program.

Study Submission and Review Process

All submissions must be made to Alexion via our online portals- Investigator Sponsor Research Portal and Externally Sponsored Collaborations Portal. If you have any questions or would like to get in touch with the local medical affairs contact for your country, please email us at datageneration@alexion.com

Please ensure that a comprehensive description of the study is provided at the time of submission as prompted by the portal. To facilitate the review by the Alexion Research Committee and minimise delays in decision making, please provide well defined study objectives and rationale. This should include explicit methods for achieving the study objectives, relevant justifications for sample size as applicable, analysis plans and timelines.

ESR Submission and Review Process



Contracting

Following approval of the study protocol by the Alexion Review Committee, Alexion will draft an ESR agreement using our legal agreement template, which will be tailored with you and your site to reflect the support being provided by Alexion and the expectations of both parties.
Alexion expects research agreements to be reviewed and signed by all parties within 12 weeks of provision of the first draft.

As a condition of accepting Alexion support for a study, the investigator will be required to:

- Report serious adverse events for studies involving human subjects
- Ensure compliance with all local regulations throughout the study
- Obtain Ethics Committee approval if required
- Submit a final study report
- Provide advance copies of all presentations and publications stemming from the work

Upon finalization of the research agreement, funding will be released in alignment with key milestone achievements as noted in the payment schedule within the research agreement.

Study Conduct

In accordance with the ESR agreement, you must notify Alexion of any updates to the study, including but not limited to:

- HA/EC approval (as applicable)
- Registration of the study in a public database (as applicable)
- Reporting of adverse events as per the ESR agreement
- Any study amendments
- Quarterly updates on the status of the study including patient enrolment, changes to study timelines and a summary of any achievements or challenges with the study.

Publications

As a research-driven company and in line with Good Publication Practice, Alexion encourages you to make every effort to publish your study results by

submitting an abstract or manuscript to a conference or peer-reviewed journal. Before any such submission, Alexion requires a draft of the publication be shared for a courtesy review at least 30 days prior to submission. Alexion support must also be disclosed in any publication.