

# Investigator Portal

## Frequently Asked Questions

**ESRO - collaboration  
that delivers results**



**es<sup>2</sup>ros**  
EXTERNALLY SPONSORED SCIENTIFIC  
RESEARCH OPERATIONS SYSTEM

AstraZeneca   
 MedImmune

# Investigator Portal

## Frequently Asked Questions



## 1 What are the types of ESR we support?

- **Interventional Clinical Research (Phase I - IV)** - Clinical, Observational Research, and/or Methodology research involving authorized, unauthorized or discontinued Company compounds no longer being developed.
- **Observational Research** (i.e. Real World Evidence (RWE)) - the product of interventional or non-interventional research, utilising data collected through observation of current clinical practice and/or patient reported experience.
- **Non-Clinical Research (pre-clinical research)** - in vitro, in vivo or ex vivo biomedical research not performed on human subjects such as: pharmacodynamic, pharmacokinetic, animal, microbiologic, human biological samples (biomarker, diagnostic assay).

## 2 What are the researcher's responsibilities in an ESR?

As the study sponsor, the researcher has responsibility for all aspects of the study, including:

- Study design
- Ensuring appropriate institutional, regulatory, and ethics committee approval
- Study conduct, including responsibility for ensuring appropriate medical safeguards, adequate record keeping, medical monitoring, adverse event reporting, and medical supervision
- Analysis, interpretation, and communication of the results (e.g. publications and submissions to conferences and journals)
- Clinical trial transparency (e.g. registration and results posting on [www.clinicaltrials.gov](http://www.clinicaltrials.gov))

For additional information regarding sponsor obligations please reference the:

- FDA website and 21 CFR 312, Subpart D
- International Conference on Harmonization E6-Guidelines for Good clinical Practice

### 3

### What does the Company require from researchers who request support of an ESR?

The Company requires you to:

- Submit a well-written proposal supported by pre-clinical or clinical data with strong scientific rationale
- Conduct a research study
- Be able to hold an IND, if necessary
- Meet proposed timelines
- Write final report or manuscript
- Provide contractually agreed-upon study status updates
- Have expert statistical support available for data analysis
- Complete all requirements of the research study agreement

### 4

### What is the proposal submission process? How and when are decisions made?

The Company accepts clinical submissions via our ES<sup>2</sup>ROS website, [https://az.envisionpharma.com/vt\\_az\\_medi/](https://az.envisionpharma.com/vt_az_medi/)

Please follow the instructions to register for a username and password to access the site.

The Primary researcher must first submit a study proposal, which is required for all ESR. Study proposals are reviewed monthly by a review and evaluation teams, which includes members from the Company Medical, Biostatistics and Regulatory local and global review and evaluation teams.

Once a proposal is reviewed and approved, the researcher will be invited to submit a full protocol for review. Please note, approval of a proposal does not imply or guarantee approval of a full protocol.

The Company review and evaluation teams assess all ESR submissions for scientific merit, statistical plan, compliance, feasibility of the proposed study design, researcher qualifications, availability of funding, and consistency with the relevant product program objectives.

ESR submissions (i.e. proposals and protocols) that are received in ES<sup>2</sup>ROS are reviewed at the next regularly scheduled monthly meeting. Decisions are typically communicated within 30-45 days of the Company's receipt of the submission.



# 5

## What information do I need to submit my study idea?

In order to submit a study idea, you will need the following information:

- A current Curriculum Vitae (CV)
- Medical license, if applicable
- Preliminary budget proposal\* (if funding is requested)
- Study hypothesis/rationale
- Objective(s)/endpoint(s)
- Treatment (if applicable)
- Sample size
- Subject eligibility
- Statistical plan

\*Please use the budget template found in ES<sup>2</sup>ROS to expedite the review of your idea.

A current CV (dated within 2 years) and, if applicable, a medical licence (US only) for the Primary Researcher must be uploaded into the attachment section in ES<sup>2</sup>ROS for the Company review process to proceed.

## Disclosures

- All requests for funding are subject to a fair market value (FMV) analysis.
- Invitation to submit a full protocol or approval of funding of an ESR should not be interpreted as a suggestion that any product is safe or effective for an investigational use or recommended for any use outside of market authorization-approved labeling.
- The Company does not guarantee that a proposal or protocol will be supported, or that funding or product will be provided. The decision to support a research project will be evidenced by full execution of a research agreement. Please note that study proposals may be submitted for 'drug only' as well as drug and funding support.
- The consideration of support for the research project by the Company is not in exchange for, nor is it intended to, induce the prescribing or recommending of any Company product.
- The Company considers proposals on a case by case basis according to the strength of the scientific and clinical rationale, and may not be able to support all requests received. Decisions regarding support for research are made at the sole discretion of the Company.
- Prior to submission to a journal or congress, the Company reserves the right to medical and legal review of all publications resulting from an approved ESR project.

