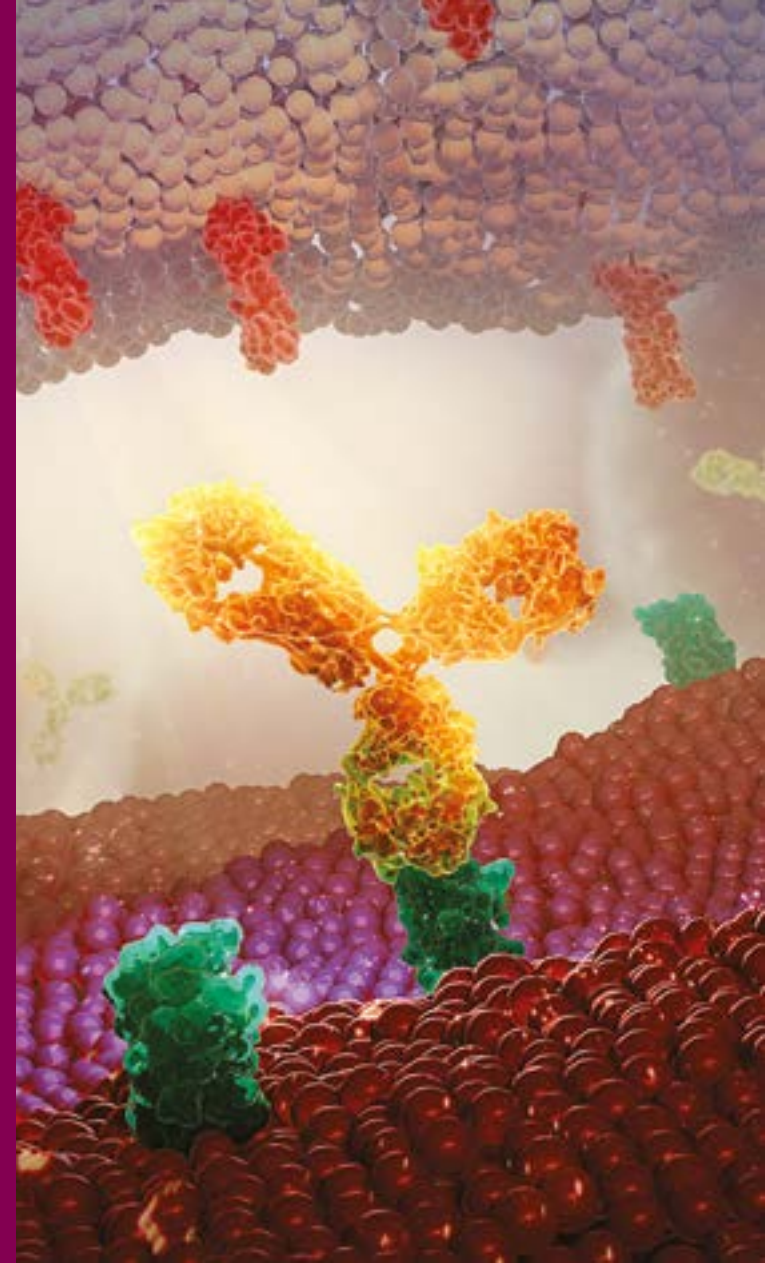


Externally Sponsored Research Handbook Oncology

The aim of this Handbook is to provide Sponsors with guidance on how to **work successfully** with AstraZeneca and to provide advice on **key challenges** in Externally Sponsored Research



Contents

Navigating this document

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Website hyperlinks

This guide contains links to online resources. Acrobat security preferences may ask you to permit access to these sites. If this is not an option, right click the link and select 'Copy URL location'. You can then enter this URL into your browser address bar to access the website.

1

Externally Sponsored Research at AstraZeneca



What is Externally Sponsored Research?

Externally Sponsored Research (ESR) is research that is initiated, designed and conducted by an independent Sponsor
It can be broadly divided into two categories

1

Investigator Initiated Sponsored Research (IISR)

IISR studies are unsolicited (unrequested) research that is planned, designed, initiated and conducted by a non-Company researcher (Sponsor).

AstraZeneca **does not assume legal and/or regulatory accountabilities, or assist** with research activities

2

Externally Sponsored Collaborative Research (ESCR)

ESCR studies are unsolicited (unrequested) or solicited (requested) research that is planned, designed, initiated and conducted by a non-Company researcher (Sponsor).

AstraZeneca **may assist** with some research activities

Within these two categories, there are three types of research



Interventional clinical research (Phases 1–4)

Clinical and/or methodology research involving authorized, unauthorized or discontinued Company compounds



Observational research (i.e. real world evidence)

The product of interventional or non-interventional research, utilizing data collected through observation of current clinical practice and/or patient reported experience



Non-clinical research

In vitro, in vivo or *ex vivo* biomedical research not performed in humans. Compounds available for non-clinical ESR are listed on AstraZeneca's [Open Innovation](#) website

AstraZeneca can support ESR by providing **product only, funding only or product and funding**

Why does AstraZeneca support ESR?

AstraZeneca recognizes the important role that ESR can play in expanding the knowledge related to a Company product and/or its associated disease area(s). This research can advance science and contribute to the development of better medicines for patients, consistent with the Company's overall research and global development strategies

Important notices

- ✓ Invitation to submit a full protocol or approval of funding should not be interpreted as a suggestion that any product/compound is safe or effective for an investigational use or recommended for any use outside of approved labelling

- ✓ 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 does not guarantee that a proposal or protocol will be supported, or that funding or a product/compound will be provided. The decision to support a research project is subject to full execution of a written Externally Sponsored Research (ESR) Agreement. Please note that submissions may request drug and/or funding support

- ✓ The Company considers submissions on a case by case basis according to the strength of the scientific 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 and are always subject to an ESR Agreement

- ✓ All requests for funding are subject to a fair market value (FMV) assessment

- ✓ The Company reserves the right to review all publications resulting from an approved ESR project, prior to submission to a journal or congress

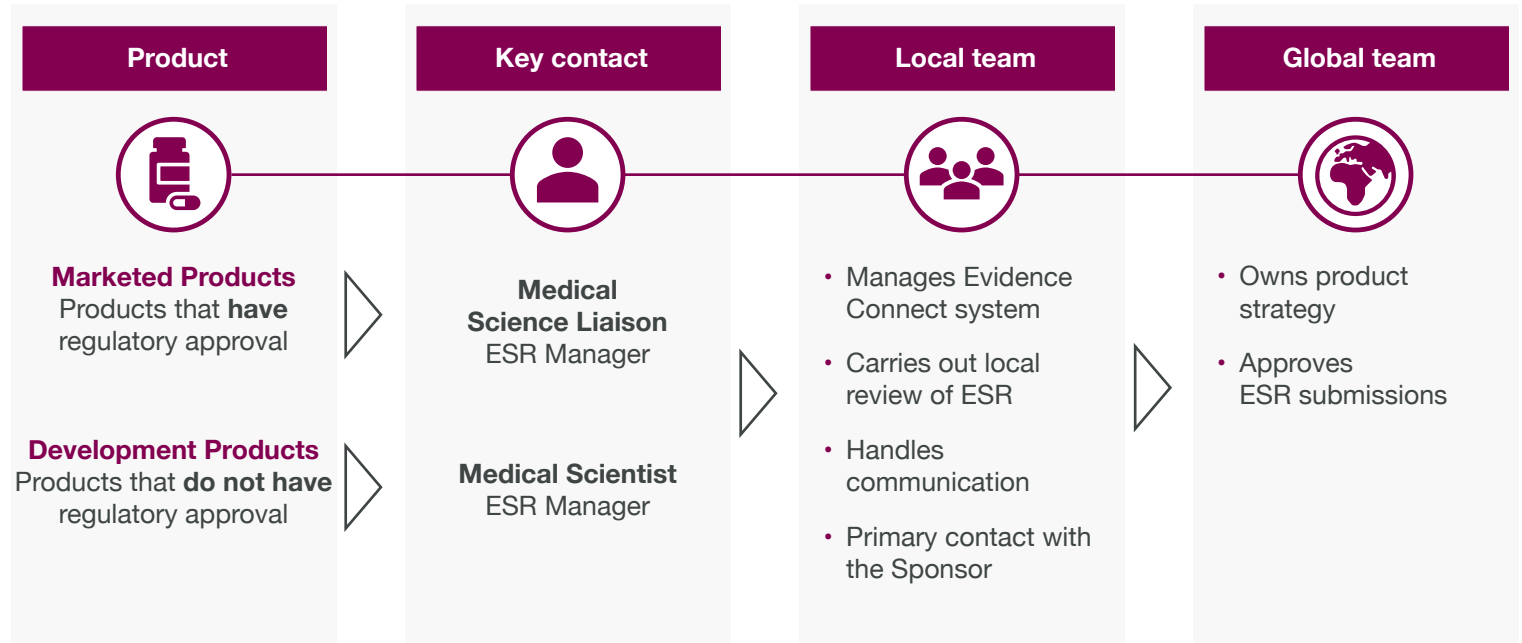
- ✓ Receipt of this Handbook does not imply or guarantee that an ESR project will be funded or supported

Who does what at AstraZeneca?

Many different people at AstraZeneca are involved in Externally Sponsored Research (ESR)

Your Medical Science Liaison will help you to find the right contact at AstraZeneca

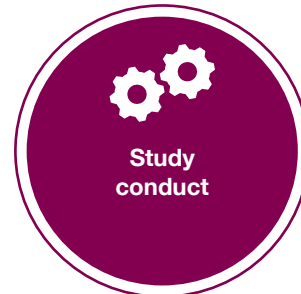
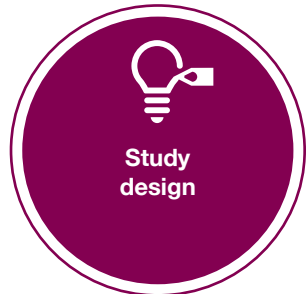
You may interact with different people at AstraZeneca depending on the development stage of a product



The [Evidence Connect](#) platform will be the **main channel of communication** between you and AstraZeneca. You will submit all information relating to the ESR using the Evidence Connect platform. Learn more about Evidence Connect in [Chapter 5](#)

Sponsor responsibilities

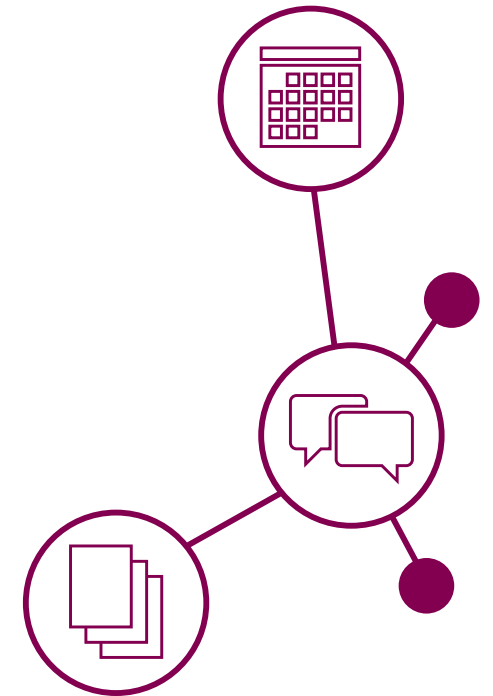
As a Sponsor you will have accountability for all aspects of the research, including the following



Please refer to **'E6 Good Clinical Practice'** on the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) [website](#) for additional information regarding Sponsor obligations for clinical studies

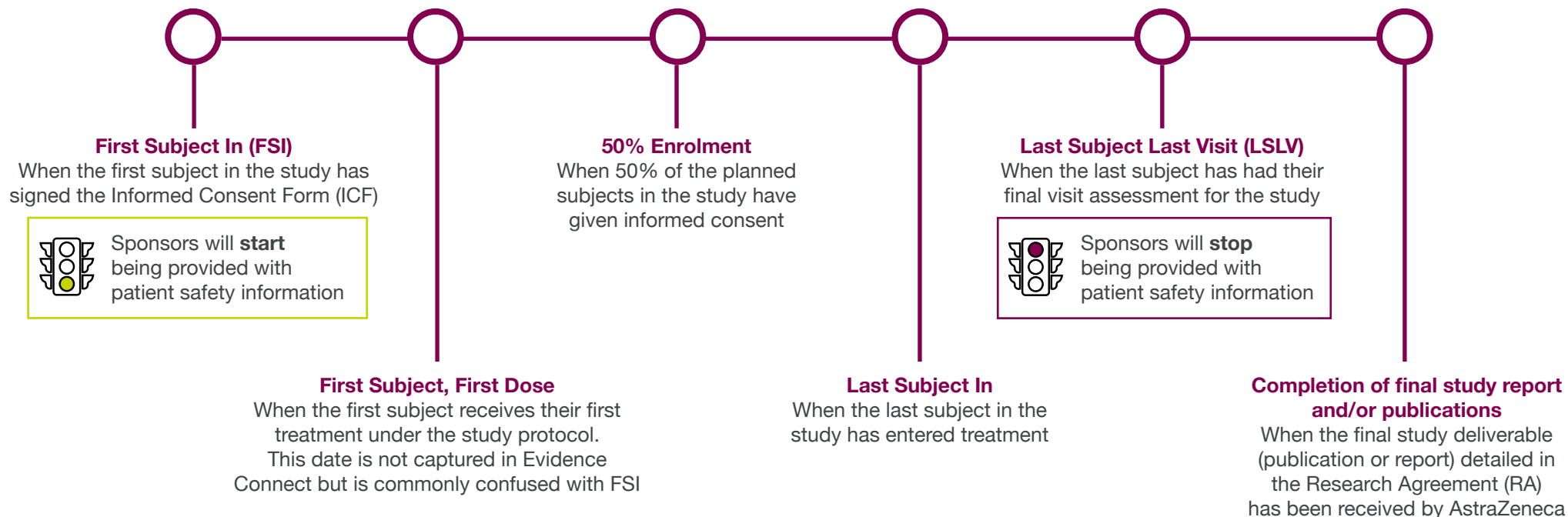
AstraZeneca's expectations of Sponsors

- ✓ Submit a well-written proposal and protocol
- ✓ Submit all documents for Company review
- ✓ Have the capabilities to conduct the research
- ✓ Submit and hold an Investigational New Drug (IND) and/or Clinical Trial Authorization (CTA), in accordance with local requirements
- ✓ Comply with the Externally Sponsored Research (ESR) Agreement
- ✓ Deliver to agreed timelines
- ✓ Provide project status updates (PSUs)
- ✓ Have expert statistical support
- ✓ Write the final report and publish the results



ESR milestone definitions

AstraZeneca measures the performance of an Externally Sponsored Research (ESR) study by assessing adherence to key **milestones**



Please note that the Company reserves the right to **withdraw funding** in the event of **significant delays** to delivery

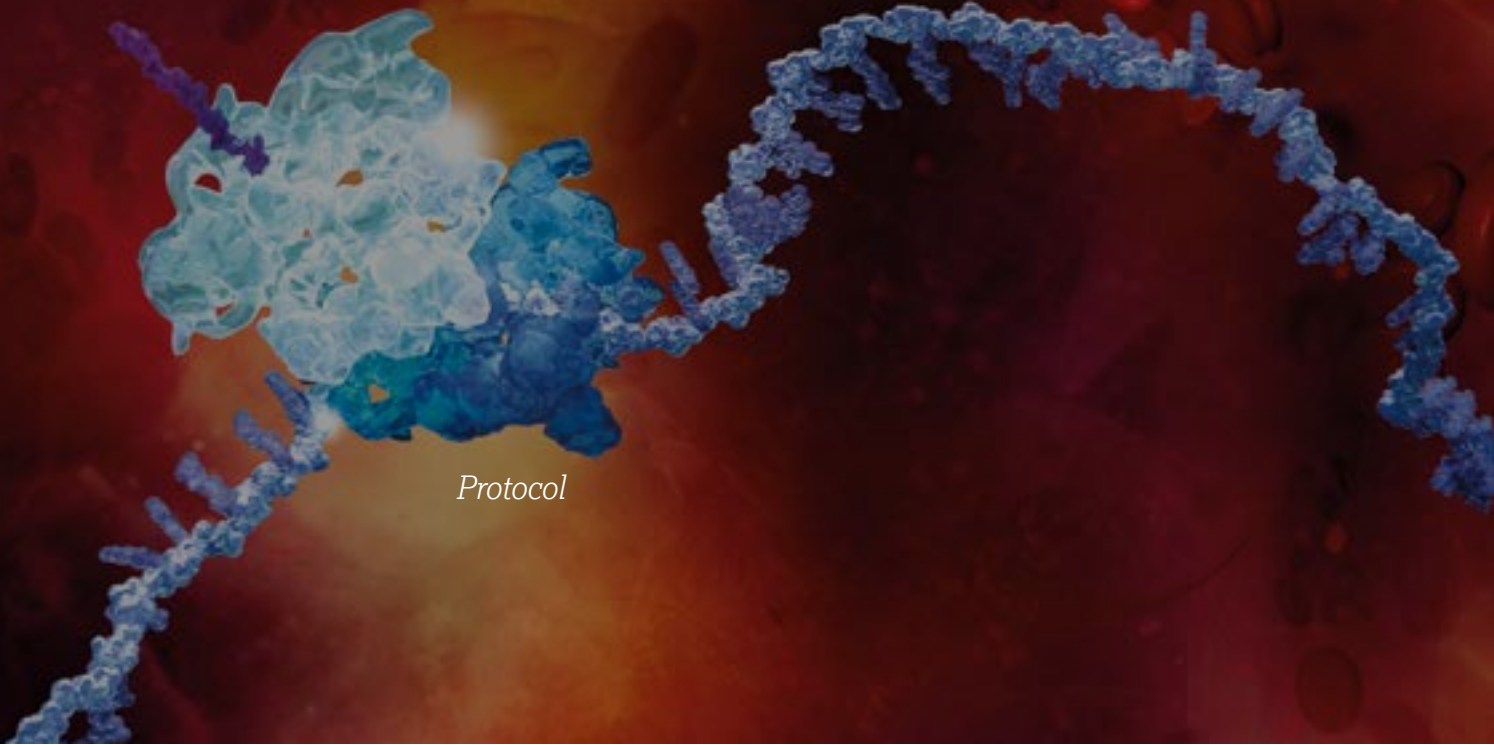
2

Design phase

Concept

Proposal

Protocol



Study concept

Development of a study concept with your AstraZeneca contact is **optional**, but feedback from AstraZeneca can inform better study design and can avoid submission of a full proposal that is off-strategy for the Company

1



Check whether the compound you are interested in is available for Externally Sponsored Research (ESR)

- AstraZeneca [Oncology compounds available for clinical ESR](#)
- Compounds available for non-clinical ESR are listed on AstraZeneca's [Open Innovation](#) website

2



Review the European Medicines Agency's Clinical Trials Information System (CTIS) guidance

- To prepare for using the CTIS, please access the [CTIS: online modular training programme](#)

3



Write an overview of your study concept, including key information

Hypothesis to be tested

- What hypothesis do you wish to explore?
- What data are supportive of the hypothesis?

Proposed study design

- Study title
- Primary objective
- Secondary objectives
- Patient population
- Sample size
- Study drugs and/or comparator
- **Schematic** of study design

Operational information

- How many sites and countries will be involved?
- How long do you anticipate:
 - for patient recruitment?
 - until the primary analysis?
 - until the interim analysis (if applicable)?
- What type(s) of support will you be requesting?

4



Next steps

- The AstraZeneca team(s) involved in your compound(s) of interest will review your concept
- You will receive a response via email and may be asked to submit a formal proposal
- A request to submit a formal proposal is **not a commitment** at this stage

Proposal submission

When you are ready to submit your Externally Sponsored Research (ESR) proposal, ensure that you register for an [Evidence Connect](#) account

You will need to provide the following information for your proposal submission

Study design information



Hypothesis and rationale



Objective(s) and endpoint(s)
Stated as measurable outcome variables



Treatment
(if applicable)



Sample size justification
Based on the primary endpoint



Patient population
(eligibility criteria)



Statistical plan

Supporting documentation



Your current CV



Medical licence
(if applicable)



Budget requested
(if applicable)



Estimated timelines



Study schematic



Submissions should **involve input from key disciplines** at your institution (statistician, research nurse, pharmacist etc.)
Please ensure that **high-quality proposals** are submitted because AstraZeneca will carry out a thorough cross-functional review

Estimating study timelines

Please ensure that your proposal includes realistic and achievable timelines for study set-up, recruitment and reporting



Protocol writing

You are expected to submit a good draft protocol **within 90 days** of proposal approval

Set-up

Typically, it takes Sponsors approximately **9 months** from protocol approval until the first patient in a study receives treatment

Recruitment

When estimating how long it will take to recruit patients for a study, Sponsors should consider the number of patients available at each stage of the screening process

Data cut-off → Data available

Work with your **statistician** to estimate how long it will take until the data cut-off for your primary objective. Include the length of time to clean, validate and analyse your data

An example of a screening cascade

Feasibility of patient recruitment

Patient population at site within the previous 12 months and anticipated referrals

Candidate for a clinical trial

Patients who do not enter competing trials

Pre-screening test

Patients who meet the eligibility criteria



Start study treatment

Pre-screening tests
If using a targeted therapy, patient numbers may be limited at this stage

Estimating study budget

Sponsors have two options for **budget development**



To use the **budget template** available from Evidence Connect



To upload an **institutional budget** using the attach file link at the bottom of the Evidence Connect screen

The **budget template** can be a useful aide to avoid missing budget items



Click **'download budget template'** to download an Excel budget template in which you can enter both direct and indirect costs



Once completed, save the template to your computer and click **'upload and extract'** to import the data into Evidence Connect



All values entered will be extracted from the Excel file and copied into a table, which you can **edit manually**, if necessary



Next, select the **currency** in which you wish to be paid, then enter the overhead percentage and the amount requested



Do not forget to forecast for **packaging, labelling and distribution (PLD)** of study drug
Remember to indicate whether you are **requesting support from additional sources**

Proposal review and approval

Once submitted, your proposal will be reviewed by the AstraZeneca team(s) involved in your compound(s) of interest

This process takes approximately **45 days**



If more details or clarifications are needed, AstraZeneca will request additional information from the Sponsor
The 45-day review target does not include time taken to provide additional information

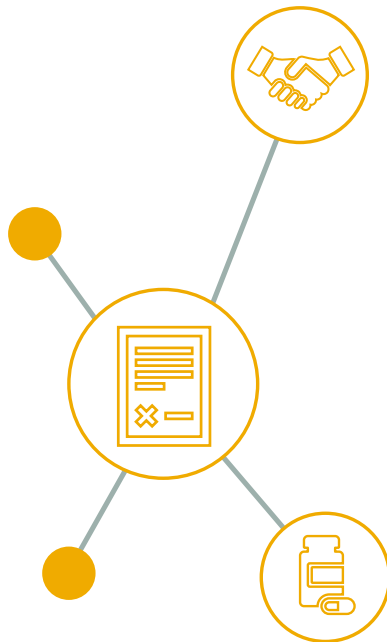


Proposals with **more than one drug** may take **longer to approve** because multiple teams need to review

Next steps following proposal approval



You will be **notified** of the decision regarding your Externally Sponsored Research (ESR) proposal by your AstraZeneca contact and through Evidence Connect



If your proposal is approved, the next step is to establish a **confidentiality agreement (CDA)**

- This is a legal contract between the Sponsor and AstraZeneca that outlines confidential material, knowledge or information to be shared between the two parties for the purpose of the ESR study

Following signature and completion of a CDA, AstraZeneca will share documents with you via Evidence Connect to support protocol development and set-up activities

- Draft **Research Agreement (RA)** to initiate contract negotiations
 - For US-based studies, the AstraZeneca Contracts Manager will provide a draft to your institution's contracting department
- Current edition of the **Investigator Brochure (IB)**
- **Protocol guidance template** for each AstraZeneca compound included in the study (if applicable)
- **Informed Consent Form (ICF) template** (if applicable)
- **Safety or toxicity** management guidelines (if applicable)

Please note that, depending on the compound(s) included in your study, you may receive multiple documents

Where applicable, you will also be reminded to obtain the following:

- **Manufacturer's Import Authorization** from the vendor responsible for secondary packaging
- **Qualified Person (QP) Release**

Protocol review and approval

If your proposal is approved, a full study protocol should be submitted to [Evidence Connect](#) within **90 days**

Once submitted, your study protocol will be reviewed:

- by the **AstraZeneca team(s)** involved in your compound(s) of interest
- against the previously approved **ESR proposal**
- against the **protocol guidance template** for each AstraZeneca compound

The protocol review process takes approximately **45 days**

The **cross-functional team** for each AstraZeneca compound will review the:

- safety management
- statistical sections
- dosing and drug supply
- translational aspects



To improve the **quality** of your first protocol draft and to minimize the length of review time:

- involve your statistician
- refer to the protocol guidance provided by AstraZeneca
- provide a justification if you deviate from the guidance provided

Once approved, you will receive a notification via Evidence Connect



If more details or clarifications are needed, AstraZeneca will request additional information from the Sponsor
The 45-day review target does not include time taken to provide additional information



Good submissions **involve input from key disciplines** at your institution (statistician, research nurse, pharmacist etc.)
Protocols with **more than one drug** may take **longer to approve** because multiple teams need to review

Next steps following protocol approval

Once your protocol has been approved, you will be provided with the following documents, where applicable

- **Letter of Access (LoA)** to be included in your Clinical Trial Application (CTA) to the regulatory authorities to allow cross-referral to AstraZeneca's Investigational Medicinal Product Dossier (IMPD) and Investigational New Drug (IND) programmes
 - Cross-referral will be against an ongoing AstraZeneca CTA
 - If there are no ongoing CTAs in your country, AstraZeneca will submit the IMPD for the study
 - For the US, please note that granting an IND programme takes ~30 days
- **AstraZeneca Manufacturer Authorization** to be included in the CTA
- A **Quality Assurance Agreement (QAA)** is needed for compounds that do not yet have marketing authorization, and this document will be sent to you and will require input from your pharmacy department
 - A QAA is only applicable to Externally Sponsored Research (ESR) studies for which an investigational medicinal product (IMP) is provided
 - A QAA is not applicable to studies for which only funding or commercial packs are provided
 - A QAA is not needed for commercial packs that are being used off label. Off label use is defined between the Sponsor and the regulators
 - However, if the intended dose is outside the commercial dose restrictions, an IMP will need to be provided
 - Note, a QAA can be part of the Research Agreement (RA)



A microscopic view of several cells, likely yeast or similar microorganisms, in a set-up phase. The cells are spherical and have a textured, bumpy surface. They are arranged in a cluster, with some cells in the foreground and others in the background. The background is dark, and there is a bright, glowing light source in the center, creating a lens flare effect. The cells appear to be in various stages of growth or division.

3

Set-up phase

Resources

You will need all of the following **resources** and/or **contacts** to run an effective clinical trial



Contracting

An Externally Sponsored Research (ESR) **Research Agreement (RA)** that complies with local laws and regulations must be negotiated and signed by AstraZeneca and the Sponsor

This occurs after protocol approval but prior to AstraZeneca providing funding and/or product, and before research can begin



Once the ESR proposal has been approved your ESR Manager will send you a draft RA

- For US-based studies, the AstraZeneca Contracts Manager will provide a draft to your institution's contracting department
- If funding is to be provided, this may include a **draft payment schedule** that does not exceed the approved amount
- Scheduled payments will be linked to ESR milestones, such as study activation, First Subject In (FSI), 50% Subject Enrolment, Last Subject In, Last Subject Last Visit (LSLV) and publication

Please note that changes to **indemnity, confidentiality, and/or intellectual property** will require review by AstraZeneca's Legal Department and will cause delay

An **RA amendment** may be negotiated to reflect scope changes throughout the study, or prior to study closure, if the full scope is not likely to be executed upon closure

Please also consider **other contracts** that you may need for the study as all third-party contracts are your institution's responsibility to negotiate

- Contracts for additional sites if you are running a multi-site study
- Contracts for other vendors
 - E.g. pharmacokinetic (PK) analysis, drug distribution and contract research organization (CRO), if applicable



Contracting is a frequent cause of significant delay in the set-up of ESR studies – we strongly recommend that you **liaise with your contracting department early in the process**

Pharmacokinetic analysis

Pharmacokinetic (PK) samples should be included only where scientifically required (e.g. novel combinations) and if treatment decisions will be based on PK data

- The Sponsor will need to contract directly with the vendor for **bioanalysis**
- Samples may be analysed at AstraZeneca's preferred vendor or the Sponsor may select another vendor
 - Please note that AstraZeneca **will not** provide bioanalytical methods, analytical standards or internal standards
 - For many registered compounds, the methodology is published, and standards are commercially available
- If data generated in the Externally Sponsored Research (ESR) study will be compared with data generated in a Company-sponsored study, it is recommended that the samples are analysed using the same bioanalytical method and at the same laboratory used by the Company



Informed Consent Form

You are responsible for developing an **Informed Consent Form (ICF)** that complies with all applicable regulation(s) on data protection
Depending on the study or compound of interest, you may be provided with an ICF template

- For Externally Sponsored Collaborative Research (ESCR), we strongly recommend that language is included in the ICFs to enable the transfer of the clinical data/samples to AstraZeneca and/or any third party contracted by AstraZeneca or the Sponsor (with no restriction on geographical location)
- Such transfers will only be made when they are agreed between AstraZeneca and the Sponsor, and specified in the Research Agreement (RA) contract



Please ensure that there are **no references to AstraZeneca as the Sponsor** included in the language of the ICF

Regulatory and other approval steps

Once the Externally Sponsored Research (ESR) protocol is approved by AstraZeneca, the Sponsor is responsible for obtaining all necessary approvals for the clinical trial as per local regulations



Generally, this includes submitting a [Clinical Trial Application \(CTA\)](#) to both **Ethics Committees** or **Institutional Review Boards (IRBs)** and **Regulatory Authorities**



Contact your ESR Manager if you receive questions from your IRB or Regulatory Authority that require AstraZeneca's support to be answered



Be aware that there may be additional committee reviews at your institution, for example:

- R&D Boards
- Radiology Boards



Once you have obtained all relevant approvals, upload the approval documentation to Evidence Connect



The investigational medicinal product (IMP) can be shipped to your site when these approvals, the Research Agreement (RA)/ Quality Assurance Agreement (QAA; if applicable) are **fully signed and available in Evidence Connect**

Drug supply



- Drug supply is free of charge to the Sponsor
- You will usually be supplied with bulk product to a single site, and will be responsible for bottling, packaging, labelling and distribution to other sites
 - Supply chain may provide bottled bulk stock if ongoing AstraZeneca studies use a suitable bottle count
- You may be supplied with commercial packs (for Marketed Products) or with investigational medicinal product (IMP)
- Matched placebo may be available for some products – ask your AstraZeneca contact to find out
 - Note, matched placebo is not available for durvalumab or tremelimumab



The **Sponsor assumes responsibility** for the IMP upon receipt

- Active management of temperature excursion
- Account for drug expiry in terms of both efficient usage and communicating future supply



- Your Externally Sponsored Research (ESR) Manager will ask you to complete an **ESR Drug Information Request Form** and will arrange the initial drug supply
 - Based on the assumptions captured in the Request Form, a forecast for total IMP supply will be generated
 - An agreed supply schedule will be developed that details the required amounts and order frequency (standard is every 6 months)
- You will be provided with a **Drug Order Form** to request the initial drug order and any subsequent reorder of the drug
 - Requests for resupply must be communicated 6 months prior to need
 - From order to receipt takes ~6 weeks; however, timelines vary for each IMP – your Supply Chain Study Manager will keep you updated
- Orders received will be compared to the forecast generated from your assumption
- Any changes to the initial assumption should be communicated to your ESR Manager to ensure effective ongoing supplies
 - E.g. changes in patient numbers, recruitment rate, treatment duration or First Subject In (FSI)

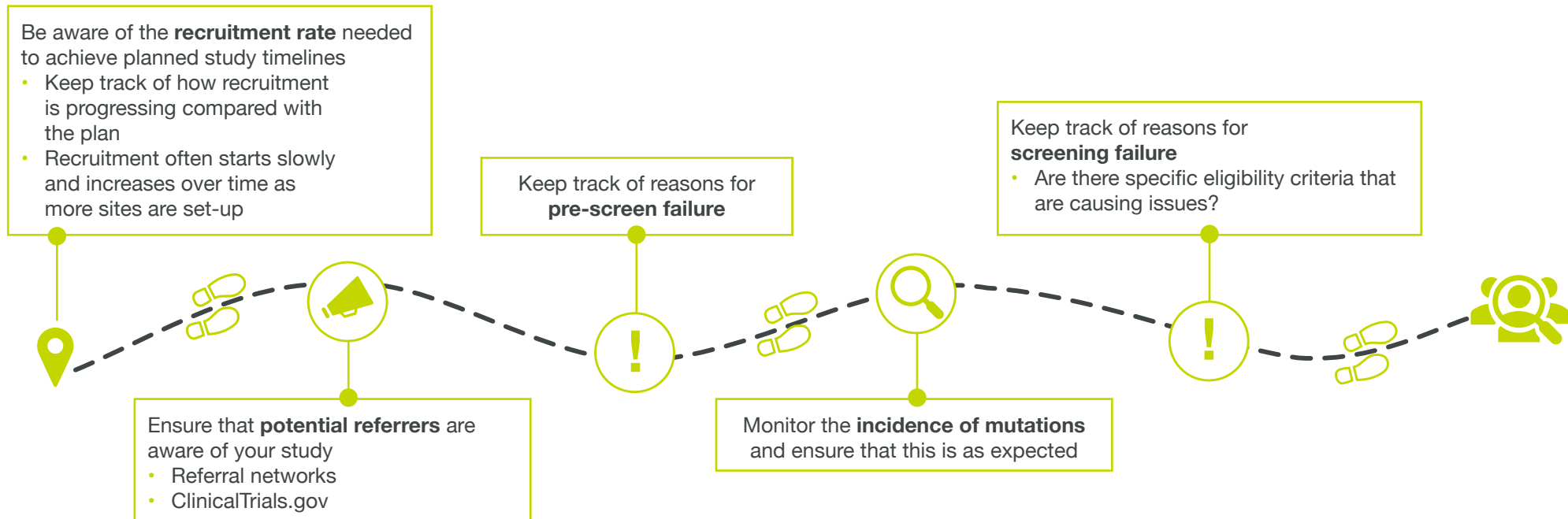
For ESR studies run as a **clinical partnership**, AstraZeneca will manage bottling, packaging, labelling and distribution via **Fisher Clinical Services**

A detailed 3D rendering of a cell membrane. The membrane is composed of a phospholipid bilayer, with various proteins and receptors embedded within it. Some receptors are shown in yellow and orange, while others are in green. The background is a soft, hazy blue and purple, suggesting an aqueous environment.

4

Delivery phase

Patient recruitment



Inform AstraZeneca if the **recruitment rate** is **slower than expected**

Data review

Consider what data you will need for **all decision-making processes** during your study



Dose-escalation studies

- Plan for the collection of dose-limiting toxicity (DLT) data
- Consider what other data you will need for decision-making
 - Will you need pharmacokinetic (PK) data, pharmacodynamic (PD) data or longer-term safety data?



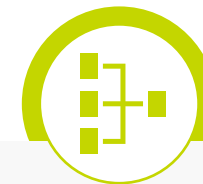
Communication

- Will data be collated before meetings or provided verbally during meetings?
- Who will be responsible for collating and/or presenting the data?



Interim analysis

- Plan for interim analysis
- At what point during the study will this take place?
 - E.g. after 'X' patients receive treatment, or after 'X' data points are collected?
- Is there a publication planned for the interim analysis?
- Are any important decisions regarding the future direction of the study reliant on interim analysis?
- Consider the statistical implications of interim analysis



Decision-making

- How much data cleaning is needed for decisions to be made?
- Who will be responsible for data cleaning?



Ensure that you understand AstraZeneca's expectations regarding **data sharing**

Safety reporting

As a Sponsor, you will be responsible for informing the Company, Health Authorities and Ethics Committees of any **serious adverse events (SAEs)** from all sites as per local requirements



The Sponsor reports **all SAEs** in accordance with regulatory requirements

- If your study is a multi-centre study, the individual sites are responsible for reporting SAEs to local authorities and to the Sponsor/coordinating site(s)
 - The Sponsor must report SAEs to the Company
- SAEs are reported to AstraZeneca using the mailboxes stated in the Research Agreement (RA)



The Sponsor is responsible for submitting a **Development Safety Update Report (DSUR)** annually, or as per local requirements, to local authorities and AstraZeneca



At the end of the study, the Sponsor is responsible for sending a comprehensive list of all SAEs to the mailbox stated in the RA

- The **safety collection vendor** is accountable for issue resolution and may contact the Sponsor as needed



The Sponsor completes **Project Status Updates (PSUs)** in Evidence Connect as stated in the RA

- State whether any SAEs have occurred within the particular time period being reported
- No individual SAE reports or SAE listings are to be uploaded to Evidence Connect at any time



Specific to studies with **durvalumab** or **tremelimumab**

- Once your protocol has been approved, you may opt to complete the imAE training module
- Please note, completion of this training is not a requirement
- Please email your AstraZeneca contact to request a link to the training

Changes during study conduct

AstraZeneca and the Sponsor are both responsible for updating the other party regarding **any changes** that may occur during the course of an Externally Sponsored Research (ESR) study



Protocol amendments

- Please ensure that all protocol amendments are submitted to Evidence Connect for AstraZeneca approval prior to submitting to the relevant Health Authority and/or Ethics Committee



Investigational Brochure (IB) updates

AstraZeneca will send any IB updates via Evidence Connect along with the following items

- A summary of the changes made
- A statement as to whether these changes are substantial or not
- An estimated date by which the Company anticipates using the Reference Safety Information (RSI) described in the IB for determining whether each adverse event (AE) should be reported to Health Authorities in an expedited manner
- Instructions about when the IB should be submitted to additional sites, relevant Health Authorities, Ethics Committees and Institutional Review Boards
 - In the UK, this would be after Medicines and Healthcare products Regulatory Agency (MHRA) approval
- New protocol and Informed Consent Form (ICF) templates, if necessary



Changes to timelines

- Milestones for ESR studies are documented in a Research Agreement (RA) prior to First Subject In (FSI)
- Sponsors are expected to deliver to their committed milestones
- However, milestones may occasionally need to be re-agreed with AstraZeneca
- If you identify a risk that your study will not deliver to the agreed milestones, please discuss this with your AstraZeneca contact and agree an action plan
 - This plan will then be discussed with the Global Team at AstraZeneca



Please note that the Company reserves the right to **withdraw funding** in the event of **significant delays** to delivery

Project Status Updates

Once an Externally Sponsored Research (ESR) study is active, the Sponsor is required to submit Project Status Updates (PSUs) at the frequency defined in the Research Agreement (RA)

All PSUs are submitted via [Evidence Connect](#)

As a Sponsor, you will need to ensure that the Company is informed of progress and is promptly provided with the following



Recruitment progress update

Summarizes the work performed and the results achieved, including number of participants (screened, enrolled, completed, withdrawn and/or in follow-up)



Milestone updates

Confirms milestones achieved (First Subject In, 50% Subject Enrolment, Last Subject In, Last Subject Last Visit) or newly proposed milestones



Safety updates

Identifies emerging safety-related issues and reports all serious adverse events (SAEs)



Publication activity

Updates the plan for any study publications

After updating the relevant information, the Sponsor should navigate to the **Active Menu** and click **'Provide Project Update'** – this will notify the ESR Manager of the submission

Why are PSUs important?

- Provides AstraZeneca with a full picture of ESR performance
- Helps to identify performance issues and facilitates implementation of corrective actions
- Ensures the timely delivery of expected study data
- Allows AstraZeneca to manage budget and product stock more efficiently



The AstraZeneca Global ESR Team can request **more frequent updates** if the study is not progressing according to agreed milestones

Data analysis

Plan your data analysis in advance – do not leave it until the end of the study before planning how the data should be analysed



Define data cut-off for **interim analysis** (if applicable)



Define data cut-off for **final analysis**



Specify whether patients will be followed up for **survival**

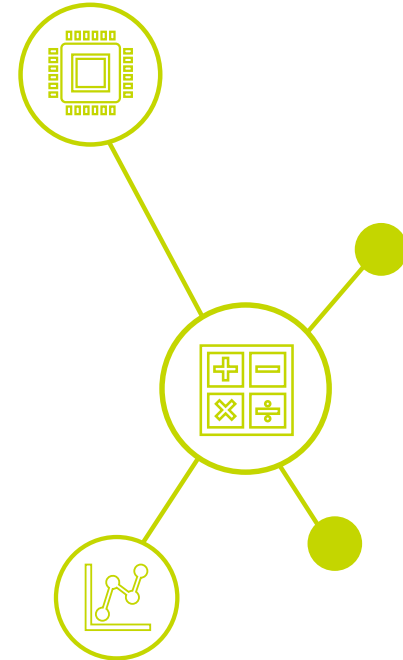
- Even if the primary endpoint is safety and tolerability



Specify the **end of the study**



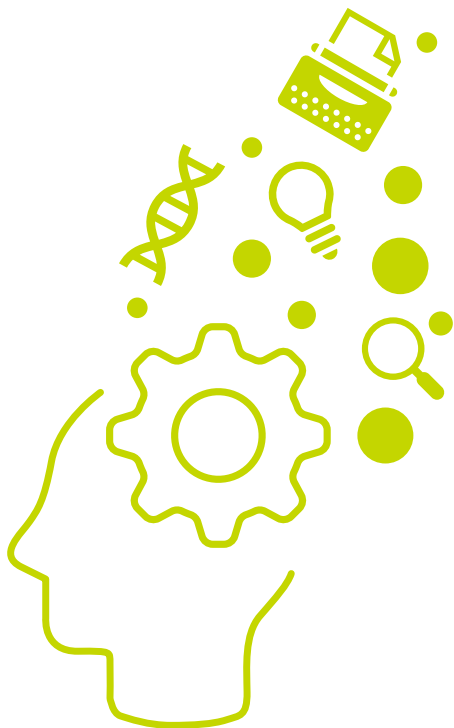
Specify **all planned analyses**



Involve a **statistician** in all aspects of data analyses

Study publication(s)

Publications resulting from Externally Sponsored Research (ESR) must abide by **Good Publication Practice (GPP)** guidelines and the **International Committee of Medical Journal Editors (ICMJE)** [recommendations](#)



- Register the study on a public clinical trial registry, post the results in the registry and publish the analyses in an appropriate scientific journal
- **Do not** include any confidential Company information in a clinical trial registry or publication
- Send all publications to the Company for review prior to submission (e.g. to a journal or conference) by uploading the publication to Evidence Connect
- Final-stage draft publications from ESR undergo review by AstraZeneca for medical/scientific accuracy, disclosure and intellectual property (IP), using the **publication sign-off (PSO)** procedure
 - PSO takes a minimum of 30 days

Investigator Initiated Sponsored Research (IISR)

- Publications must be developed independently of Company influence
- No Company authors or co-authors
- Final-stage draft publications from IISR require only PSO review

Externally Sponsored Collaborative Research (ESCR)

- The Company's employees may be involved in:
 - planning and developing ESCR publications
 - editing and medical writing assistance
 - authorship
- Final-stage draft publications from ESCR that involve Company author(s) require both PSO review and PSO approval signature



Please also submit a copy of the **final version of the publication** to AstraZeneca

5

Evidence Connect

Evidence Connect

The **Evidence Connect** platform is AstraZeneca's electronic system for processing Externally Sponsored Research (ESR) submissions, and for tracking and managing ongoing ESR studies



Evidence Connect is used for:

- ✓ proposal submission and approval
- ✓ protocol submission and approval
- ✓ Project Status Updates (PSUs)
- ✓ publications

- The Evidence Connect platform has been designed to offer Sponsors a fast, user-friendly and secure way to submit and to track ESR studies
- Evidence Connect is the main channel of communication between you and AstraZeneca
- Please note that submissions to Evidence Connect must be made in English
 - For help with how to use Evidence Connect, please refer to the Evidence Connect [User Guide](#)

- Before accessing Evidence Connect, please watch the short training videos on the [Evidence Connect Training Centre](#)
- Then follow the **'make a submission'** link to register a new [Evidence Connect](#) account