Overview – How to create and submit an ESR study proposal

1 **Log in to VCV**

ESR Info ▾

In the Homepage click **ESR Info** top left and select **Externally Sponsored Research** from the drop-down menu.

2 Read **AZ's Terms and Conditions** in the **Acknowledgements** section and tick **'I agree, etc.'**

3 Open the **General Information** section and complete the mandatory fields:

- Study Type
- Study Title
- Short Title
- Therapeutic Area
- Indication
- Tumor Type (Oncology studies)
- Primary Product
- Type of Support
- Primary Country
- Number of Sites
- On Label
- Have you contacted anyone in AZ?
- Support from outside AstraZeneca?

Note: For this and subsequent sections, use the **pencil icon** top right to open the fields and click **Save** when you have completed them.

4 When above fields have been completed and saved, a unique study number is created, and the study enters the **'Proposal Not Submitted'** lifecycle state and more sections show up to be filled in.

5 Open the **Proposal Synopsis** section and complete the mandatory fields:

- Primary Objective
- Secondary Objectives
- Primary Endpoint
- Secondary Endpoint
- Inclusion Criteria
- Exclusion Criteria
- Hypothesis
- Rationale
- Population
- Sample Size Justification/Statistical
- Treatment regimen
- Project Start to Completion (in months)
- Project Completion to FSR (in months)

9 Open the **Publications** section. Complete the mandatory fields:

Note: At least one planned publication is mandatory.

- Publication Category
- Publication Type
- Publication Date
- Journal/Congress

8** Open the **Budget/Support Information** section and complete the mandatory fields:

- Requested Currency
- Total Amount Requested

7* Open the **Investigational Products** section and complete the sub-section mandatory fields:

Primary product is automatically created in the Investigational Products section

- Product
- Dosage Formulation
- Dosage Strength
- No. of Subjects
- Quantity

6 Open the **Study Information** section and complete the mandatory fields:

- Design Characteristics
- Study Phase
- Blinding
- Randomisation
- Safety Listings requires?
- Are there Additional Countries?
- Planned No. of Enrolled
- Planned No. of Entered Treatment
- Planned No. of Completed

* This section is only applicable when the Product is requested

** This section is only applicable if funding is requested

10 Open the **Primary Investigator & Site** Information section. Complete the mandatory fields:

Note: Once the information is added it automatically shows up in the Site Personnel and Sites sections. Further personnel and sites can be added to those sections.

- Primary Investigator (External) – a pop-up Search box will show up but a new record must be created if the name is not included in the list.
- Primary Site (External) – a pop-up box will show up.

11 + Add

Open the **Related Documents** section.

To add mandatory **PI CV** and **Budget**, click **+Add.** When the pop-up box shows up, click **Create** and follow steps to upload and identify the documents required.

+ Create ▾

12 The **Submission Checklist** enables you to make sure you have included all the documents required. To check the boxes you must first click the **pencil icon.**

13 Go to the **workflow icon** top right and select **Submit Proposal** from the drop-down menu.

Note: If any mandatory information is missing, an error message will list the missing items.

14 When the study is in the **Proposal in review** lifecycle state, you will be notified by AZ if additional information is required for the study.