Overview – How to create and submit an ESR study proposal

1 Log in to VCV

On the Homepage, click **ESR Info** tab and select **Externally Sponsored Research**. Click **+Create** top right.

ESR Info

+ Create

2 Please review **AstraZeneca's Terms and Conditions** in the **Acknowledgements** section, then select **'I agree with the statement above'** to confirm your acceptance.

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: To complete this and the following sections, utilise the **pencil icon at the** top right to access the fields and click **Save** once you have finished entering the information.

4 Once the above fields have been completed and saved, a unique study number is generated, and the study transitions to the **'Proposal Not Submitted'** lifecycle state, allowing more sections 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
- Contract Execution to FSI (in months)
- FSI to 50% Enrollment (in months)
- 50% Enrollment to LSI (in months)
- LSI to LSLV (in months)
- LSLV to FSR (in months)

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

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

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
- Total Quantity

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

- Requested Currency
- Total Amount Requested

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

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

Note: At least one planned publication is mandatory.

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

- 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

Note: Once the information is added, it will automatically appear in the **Site Personnel** and **Sites** sections. Additional personnel and sites can then be added to those sections.

11 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.

+ Add

12 The **Submission Checklist** enables you to ensure that all required documents are included. 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 During the **Proposal in Review** lifecycle state, AstraZeneca will notify you if additional information is required for the study.

* This section is only applicable when the Product is requested

** This section is only applicable if funding is requested