

Resources for paticipants

This document outlines the materials that are available for use throughout the Valor Study for participants and parents/caregivers. These resources aim to accelerate recruitment, facilitate enrollment, and aid in retention. All materials are available in local languages for all countries in the Valor Study.



Pre-consent resources

1-Recruitment Poster: An illustrative poster for display at participating sites promoting the study to potential participants. This poster is intended to keep the study at the top of mind among site staff, raising awareness and promoting the study opportunities, while inviting potential participants to speak with site staff about involvement in the Valor Study.

2-Patient Letter: A letter for sites to provide for potential participants to assess study interest. The patient letter provides information on the purpose of the Valor Study and what happens during the trial. This letter is a recruitment tool intended to be distributed pre-consent.

3-Study Website containing Understanding the Valor Study video: A website for potential participants to reference containing information on the study schedule, a high-level overview of procedures and tests, side effects and risks, and the voluntary nature of the study. This website will host the Understanding the Valor Study video which educates potential participants on the Valor Study and what can be expected if they decide to join the study. The video can be used during recruitment and throughout the duration of the study.

4-HCP Referral Letter and Fact Sheet: A double-sided letter and fact sheet that introduces the study design, rationale, goals, and inclusion and exclusion criteria in a clinical fashion to referring colleagues. This letter explains the referral process and study activities, inviting HCPs to consider if any of their patients may qualify to be referred for participation. This letter is a recruitment tool intended to be distributed digitally.

Post-consent resources

5-Study Schedule Planner: An illustrative book that explains the purpose of the Valor Study to participants. This material informs participants of what to expect for study-related procedures and tests, the study schedule, side effects and risks, and the voluntary nature of the study. It is intended to be distributed at consent.

6-Thank You Card: A printed thank you card to send a personal message of appreciation to participants at any time during their participation in the Valor Study.

7-Wallet Card: A card to provide to participants as an official record of their enrollment in the Valor Study. It contains contact information for the study site staff to be used if more information is needed about the study, and in the event of an emergency or adverse event.

Site-facing resources

8-Ring Cards: A set of five double-sided 5" x 7" quick reference ring cards to be used during enrollment by study coordinators and additional site staff to aid in pre-study activities. This material lists inclusion/exclusion criteria from the protocol for site staff to review and confirm participant eligibility for the Valor Study.