General Information		
A	**Requestor**	
A	**Request Date**	
A	**Bioverativ Medical Contact**	
A	**Tracking Number**	
A	**Proposal Type**	☐ Investigator Initiated Trial (Investigator is Regulatory Sponsor) and only funding, samples, or data are requested from Bioverativ) ☐ Sponsored Research Agreement Study (Investigator is Regulatory Sponsor) ☐ Company Sponsored Trial (Bioverativ is Regulatory Sponsor)
A	**Study Type**	☐ Clinical Interventional ☐ Clinical Noninterventional ☐ Nonclinical / Data Analysis
A	**Primary Site Location** (List the geographical location of the primary site where the study will take place. Select from options in the drop down list in VisionTracker).	

Product Category		
Indicate which product or disease state the study is investigating. If the study is not investigating a specific product, or investigating multiple products, select General Hemophilia. For Bioverativ Areas of Interest, see: http://medicalresearch.Bioverativ.com		
A	**Rare Diseases Category**	☐ Alprolix® ☐ Eloctate® ☐ General Hemophilia
	Study Title	

Support Information		
A	**Type of Support**	☐ Product ☐ Funding ☐ Product and Funding ☐ Lab Samples and/or Data Sets Only
A	**Local Currency Type**	
A	**A - Total Budget Requested (Local)**	

A	**Drug Request Category**	☐ Commercial (Reimbursable) ☐ Commercial (Investigational – Bioverativ provided) ☐ Clinical (Investigational – Unlabeled – Bioverativ provided) ☐ Clinical (Investigational – Labeled – Bioverativ provided) ☐ Matching Placebo ☐ Ancillaries or Comparators
A	**Additional Drug Supply Support Requested**	☐ Labeling and Packaging ☐ Interactive Voice Response System ☐ Multisite Distribution and Centralized Storage
B	**Is a dataset being requested?**	☐ Yes ☐ No
B	**Are laboratory samples being requested?**	☐ Yes ☐ No
A	**Is additional study supporting being requested?**	☐ Yes ☐ No
A	**If yes, select type**	☐ Statistical ☐ Data Management ☐ Sample Analysis ☐ Medical Writing ☐ Vendor Management ☐ Study Management ☐ Project Management ☐ Other
A	**If other, please specify**	

Study Contacts		
Principal Investigator's Details *(The PI is responsible for conducting the research)*		
A	**Principal Investigator's First Name**	
A	**Principal Investigator's Last Name**	
A	**Principal Investigator's Suffix**	
B	**Principal Investigator's Institution**	
B	**Address**	
B	**Address 2**	
B	**City**	
B	**Postal Code**	
B	**Province**	
B	**Phone Number**	
B	**Phone Extension**	
B	**Fax Number**	
B	**Email Address**	
Study Site Information (If same as "Principal Investigator's Details", enter "Same as above")		
B	**Single/Multi-Center**	
A	**Primary Site Name** (List institutions where the proposed research will be conducted)	
B	**Contact Name**	
B	**Site Address**	
B	**Site Address 2**	
B	**City**	
B	**Postal Code**	
B	**Province**	

B	**Site Phone Number**	
B	**Site Phone Extension**	
B	**Site Fax Number**	
B	**Contact Email Address**	
B	**Unique ID**	
B	**Unique ID Type**	
Drug Shipment Information (If same as "Study Site Information", enter "Same as above")		
B	**Ship to**	
B	**Contact Name**	
B	**Shipping Address**	
B	**Shipping Address 2**	
B	**City**	
B	**Postal Code**	
B	**Province**	
B	**Phone Number**	
B	**Phone Extension**	
B	**Fax Number**	
B	**Contact Email Address**	
Additional Personnel and Site Information		
Additional Personnel		
B	**Role**	
B	**Name**	
B	**Phone**	
B	**Fax**	

Additional Sites		
B	**Site Type**	
B	**Site Name**	
B	**Contact Name**	
B	**Phone Number**	
Study Categorization		
A	**Subjects** (Patient Population)	☐ Hemophilia Type A ☐ Hemophilia Type B ☐ All forms of Hemophilia ☐ Other
A	**Study Design** (Check any and all categories that apply to the proposed study design)	☐ Prospective ☐ Retrospective ☐ Open Label ☐ Cross Over ☐ Randomized ☐ Double Blind ☐ Single Blind ☐ Other
	If Other, please specify	
Project Study Milestones		
A	**Total Study Duration** (Months)	
A	**Planned Start** (Estimated # of months from approval to study start)	
B	**Final data available after study completion** (Months)	
Planned Subject Information – Required for Clinical Studies Only		
B	**Total Number of Subjects**	
B	**Planned Enrollment per month**	
B	**Total Subject Exposure** (months)	
B	**Total Subject Follow-up** (months)	

Detailed Study Information		
A	**Study Rationale** (includes rationale and supporting evidence to justify hypotheses. This may come from scientific gaps that exist in published literature, current unmet medical needs or emerging treatment patterns, previous or pilot data you may have generated, or some combination of these)	
A	**Primary Objective** (Identify the objectives of your proposed study)	
A	**Additional Objectives**	
A	**Primary Endpoint** (Identify which specific endpoint you will use to meet each objective. Present each endpoint as a measurement (e.g. difference between treatment groups, change from baseline, correlation between Y and Z variables over a specified time period)	
A	**Additional Endpoints**	
B	**Inclusion Criteria** (For research involving human subjects, list the inclusion criteria that will dictate enrollment into your study. Present the information in bullet format if possible)	
B	**Exclusion Criteria** (For research involving human subjects, list the exclusion criteria that will dictate enrollment into your study. Present the information in bullet format if possible)	

B	**Study Method/Design** (Carefully explain how your proposed study will be conducted in a coherent and logical manner. For example, if a parallel arm(s) design is planned, clearly distinguish each of arm of the study by the treatment intervention to be applied, what controls will be incorporated, what data will be collected, and the length of time that observations will be made. Feel free to upload a study diagram, schematic, or schedule of events if you this will properly convey your design. If specialize equipment, therapeutics, antibodies, reagents, or sources of data will be utilized, prove enough detail so reviewers will be able to determine whether these are adequate to achieve the objectives of your proposed study. If applicable, please indicate where the patient population is being drawn from (i.e., please specify which clinical patients registries, databases, etc. are planned to be used for the study). For data analysis, provide a detailed description of the dataset to be analyzed)	

In the following two fields, explain and define statistical considerations. Statistical considerations should address two major aspects of your proposed study: (1) determination of the sample size, and (2) the analysis plan. The sample size should be based on the primary endpoint, and details on how the same size was determined should be provided. The power to detect and effect should be stated, or clearly identify if your proposed research is exploratory (pilot) in nature and accurate power calculation cannot be determined. With respect to the analysis plan, provide enough detail on the specific methods and tests that will be utilized so the reviewers will be able to determine if they are appropriate for the type of data that are being collected.

A	**Estimated Sample Size**	
B	**Sample Size Justification**	
B	**Statistical Analysis Plan**	
B	**Do you plan to present data from the proposed study at any scientific congresses or professional societies?**	☐ Yes ☐ No

B	**Do you plan to publish data from the proposed study in peer-reviewed scientific journal?**	☐ Yes ☐ No
B	**References** (Provide a bibliography of only the references published / presented research that was cited in your study proposal)	
B	**Comments**	

B- Additional Information – Tables and Graphs (Optional)

Provide tables and graphs as attachments. Ensure each is appropriately labeled and/ or referenced.

B - Signature

By signing this form, I certify that the above is an accurate and complete record submission.	_____ Principal Investigator	_____ Date