Data Management Plan

A Phase 3 Open-Label, Single-Arm Study To Evaluate The Efficacy and Safety of BMN 270, an Adeno-Associated Virus Vector – Mediated Gene Transfer of Human Factor VIII at a dose of 4E13 vg/kg in Hemophilia A Patients with Residual FVIII Levels ≤ 1 IU/dL Receiving Prophylactic FVIII Infusions

270-302

BMRN 270

09-APR-2020

Protocol Number: 270-302

Product: BMRN270

Author: Cosmas Collins

Version: 2.0

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Definitions and Abbreviations

Term/Abbreviation	Definition
ACE	The Analytic Computing Environment, a UNIX system containing study datasets, is the programming environment established within the SAS System under which the Biometrics department accesses clinical data and conducts analyses of those data in support of its clinical trial project deliverables.
BPV	BioMarin Pharmacovigilance
CCG	CRF Completion Guidelines
CP	Clinical Programmer
CDM	Clinical Data Manager
CLO	Clinical Operations
CLS	Clinical Science
CRA	Clinical Research Associate
CTMS	Clinical Trial Management System; CTMS contains investigator-related information and information from daily Interactive Response Technology (IRT) transfer.
DAP	Data Access Plan guides access to and management of the study data
DD	Database Developer
DMC	Data Monitoring Committee; An independent committee established by the sponsor to assess at intervals the progress of a clinical study, the safety data, and/or the critical efficacy endpoints, and to potentially recommend to the sponsor whether to continue, modify or stop a study.
DQRL	Data Quality Review Listing that facilitates data review to identify potential discrepancies.
eCRFs	Electronic Case Report Forms
EDC	Electronic Data Capture
Essential Documents	Paper and/or electronic records that, in accordance with federal regulations and the International Conference on Harmonization (ICH) Guideline for Good Clinical Practice (GCP), individually and collectively permit evaluation of the conduct of the study and the quality of the data produced. Specifically, essential documents are those listed in the ICH Guideline for GCP, E6 Section 8.
DMP	Data Management Plan
GCP	Good Clinical Practices; A standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical studies that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of study subjects are protected.
Medidata Rave	Medidata Rave is an Electronic Data Capture system used for clinical data collection. The collected data are stored in Biometrics' Analytic Computing Environment (ACE).
MedDRA	Medical Dictionary for Regulatory Activities; International medical dictionary terminology developed under the auspices of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).
PI	Principal Investigator

SAE	Serious Adverse Event
SEM	Schedule of Events Matrix; Document defining the name of each form/page within the eCRF and the study visit(s) at which each form should appear.
SP	Statistical Programmer
TMF	Trial Master File; A file that contains the key records (including essential documents) relating to a clinical study (e.g., clinical protocol, blank Case Report Form[s], IRB/EC documents, contact reports, etc.). During the study, the file may be split across more than one location (e.g., some records may be held at BioMarin and some at a CRO). Electronic copies of TMF records from new studies are stored in BioMarin's Veeva Vault eTMF.
WHO Drug	World Health Organization Drug Dictionary; An international classification of medicines created by the WHO Programme for International Drug Monitoring and managed by the Uppsala Monitoring Centre.

1.0 Purpose

1.1. The Data Management Plan (DMP) is an overview of the data management quality processes performed during the conduct of a clinical trial and is developed based on the protocol, standard CRFs, and other study-specific or department-specific forms and requirements for the study.

1.2. The DMP is a "living" document that is updated as needed throughout the course of the study. Administrative changes are captured in the Log of Changes found in the DMP Appendix and communicated to the study team per the *Development of the Data Management Plan SOP*.

1.3. Modifications to documentation supporting the DMP (e.g., Edit Check Specifications [ECS], CRFs, etc.) are re-signed independent of the DMP according to specific SOP and Work Instruction requirements.

2.0 Data Working Group

Name	Role	Start Date	Email
Ann Mikhail	Assoc Director, DM Program Lead	Aug-2019	ann.Mikhail@bmrn.com
Cosmas Collins	Lead Project Data Manager	Jan-2018	cosmas.collins@bmrn.com
Alexa Rodriguez Prieto	Principle II, Database Developer	Jan-2017	alexa.r.prieto@bmrn.com
Chunzi Zhang	Clinical Data Programmer II, Clinical Programming	Jan-2017	chunzi.Zhang@bmrn.com
Raj Sharma	Principle II, Stats Programming	Jan-2017	raj.Sharma@bmrn.com

Lorna Fang	Director, Stats Programming	Jan -2017	lorna.fang@bmrn.com
Tony Chang	Sr. Director, Stats Programming	Jan-2018	tony.chang@bmrn.com
Ben Kim	Executive Director, Medical Monitor	Jan-2017	ben.kim@bmrn.com
Goutham Chinnapolamada	Director, Statistical Programming	Jan-2017	GChinnapolamada@bmrn.com
Laurie Hsiao	Pharmacovigilance Operations Lead (BPV)	Jan-2017	laurie.hsiao@bmrn.com
Katie MacQuien	Sr Clinical Trial Manager, CLO	Jan-2017	katie.macquien@bmrn.com
Jayson Andrews	Assoc Director, CLO	Jan-2017	jayson.andrews@bmrn.com
Xinqun Yang	Executive Director, Biostatistics	Jan-2017	xinqun.yang@bmrn.com
Mei Huang	Associate Director, Biostatistics	Apr-2019	Mei.Huang@bmrn.com
Adebayo Lawal	Sr. Medical Director, Medical Monitor	Jan-2017	adebayo.lawal@bmrn.com
Denis Mir	Director, CLO	Jan-2017	DMir@bmrn.com
Annie Chang	Project Manager	Jan-2017	achang@bmrn.com
Oscar Alcantar	Sr Clinical Trial Manager, CLO	Jan-2020	oscar.alcantar@bmrn.com
Lucy Ball	Clinical Trial Manager, CLO	Jan-2017	LBall@bmrn.com
Danielle Allison	Senior Clinical Trial Specialist, CLO	Apr-2018	danielle.allison@bmrn.com
Kala Jayaram	Sr. Medical Director, BPV Safety Science	Jun 2018	KJayaram@bmrn.com
Urooj Imtiaz	Assoc Medical Director, Safety Scientist	Apr-2019	urooj.imtiaz@bmrn.com
Reena Mahajan	Associate Medical Director, Medical Monitor	Oct-2019	Reena.Mahajan@bmrn.com

3.0 Responsibilities

3.1. Clinical Data Manager (CDM). The Clinical Data Manager has overall responsibility for managing and verifying that data within the database have been reviewed and cleaned

appropriately as defined by the Edit Check Specifications, Data Quality Review Listings (DQRL) specification and Manual Review specification. In the context of this overall accountability, other study team members bear function-specific responsibility to ensure data quality based on their areas of expertise. Team members will enter their queries into a Query Log placed on the study SharePoint, and CDM will issue the queries to site.

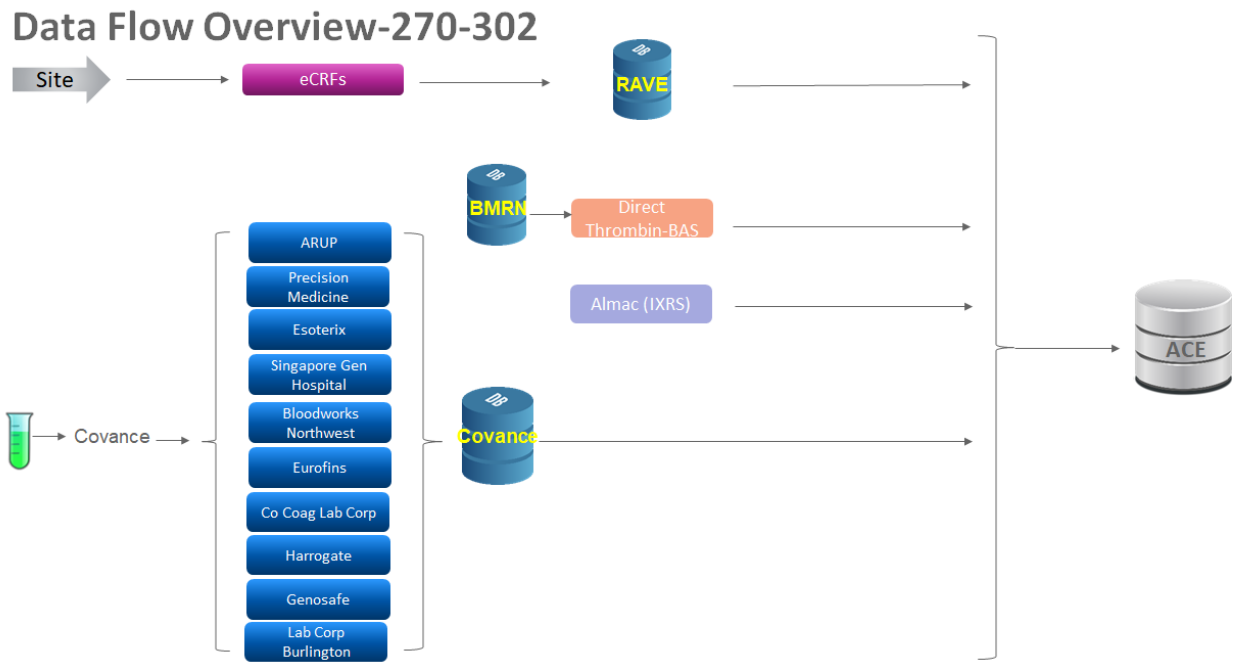
3.2. Clinical Sciences (Medical Monitor). The Medical Monitor has the responsibility for reviewing data for subject safety, safety data trends and for providing input on issues that require medical judgement. This review will be done under the guidance of the Data Access Plan (DAP) and the DAP Communications Plan. The DAP is included in appendix B

3.3. Biostatistics, Statistical Programming and Analysis or designee. The Biostatistician and Statistical Programmer will review the data for CDISC SDTM compliance and logic. They will review the data as it pertains to the Statistical Analysis Plan and review listings for outliers that may affect the data that will be presented in the TLGs and other statistical deliverables.

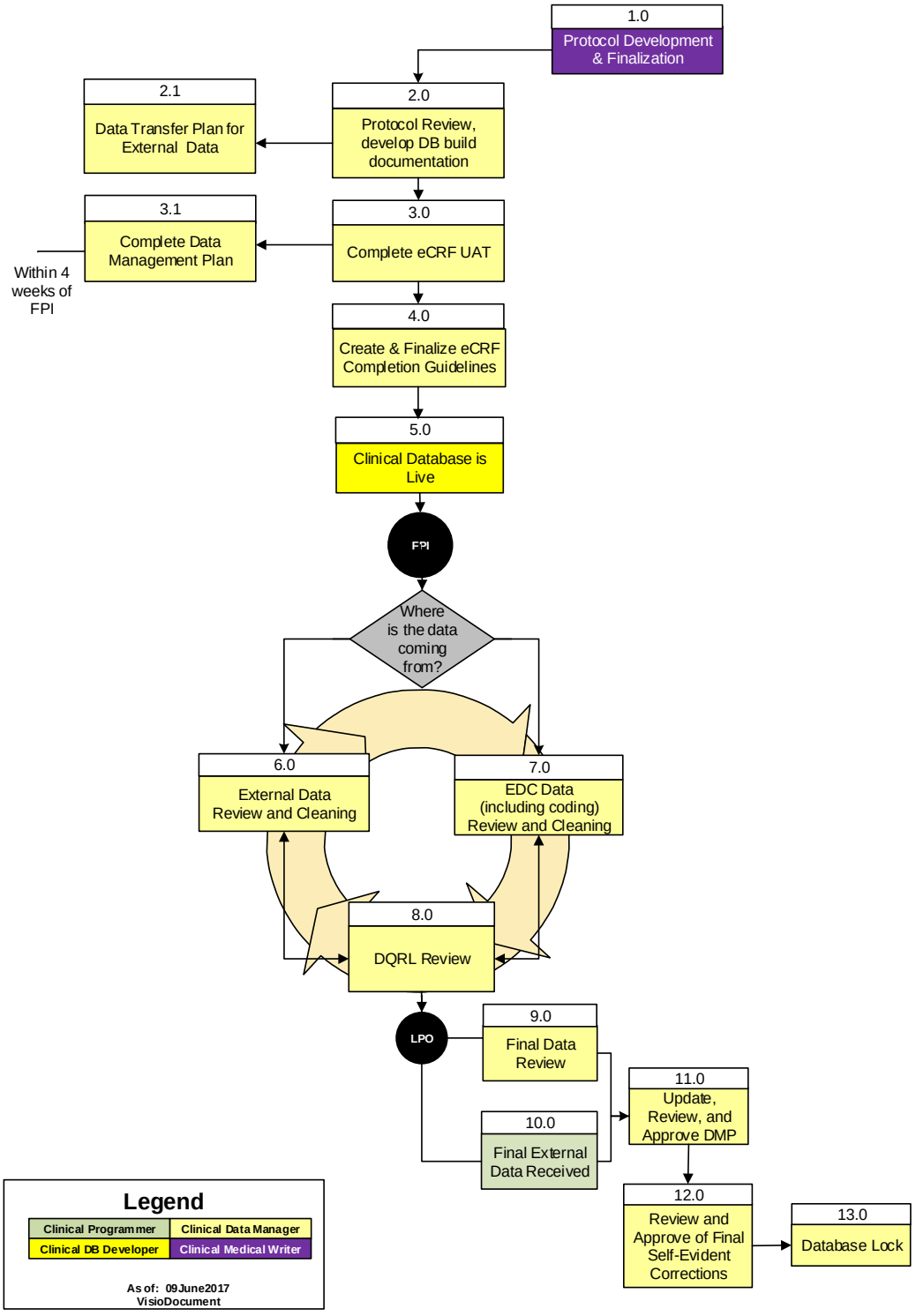
3.4. Clinical Operations (Study Team Lead) or Designee. The Study Team Lead will review data to identify Protocol Deviations or other site conduct issues (e.g., Drug Lot Number discrepancies). This will be done under the guidance of the DAP.

4.0 Data Sources and Data Management Workflow

The following sources of data are used in this study.



The following process map outlines the main activities in the study: for more detailed please see section 12 external data transfers



5.0 Data Security

5.1. BioMarin clinical databases are supported by Medidata. Security best practices are employed to ensure data security as specified within the Medidata Information Security and Privacy White Paper. Refer to this document for detailed policy and accreditation/certification information in relation to Network Security Application Security, Data Privacy, and Business Continuity and Disaster Recovery Planning.

6.0 Data Entry

6.1. Study site personnel with EDC write access to the study database enter the clinical study data into the eCRFs and resolve any resulting system-generated or manual queries according to the study-specific CRF Completion Instructions. Study site personnel are trained, as specified by BioMarin, on all necessary entry conventions.

Associated Documents: BMT-01-TMP-004, Standard CRF Completion Instructions Template

7.0 Data Review and Cleaning

7.1. Data validation for this study is performed according to the study DQRL specifications, edit check review and review of manually issued queries. Critical data was the primary focus of data validation, specified in the table below.

7.2. Critical Data

7.2.1. In this study, the following forms and fields are considered critical:

Form	Field	Related Endpoint / Comment
Adverse Events	All	Safety
Bleed History	All	Number of Annualized bleeds experienced by the subject prior to dosing with BMRN270
Bleeding Log	All	Number of annualized bleeds experienced by the subject after dosing.
Missed Work/School	All	There should be a Work/School form for every Bleeding log form completed
Factor VIII Infusions	FVIII dosing	Number of doses of Historic prophylactic FVIII and the Number of FVIII required after administration of the study material.
Subject Disposition	Date, reason	Study disposition; study follow up time used to calculate annualized bleed rate/FVIII usage.
Study Drug Administration	All	Dose of study drug administered; follow up time used to calculate annualized bleed rate/FVIII usage.
External Lab Data (Covance)	FVIII levels and LFT all data to be reconciled	Safety and Efficacy

8.0 Query Management

8.1. "System Edit Checks/Electronic Edits" (EE) fire when the entered data do not meet the programmed criteria. The site can resolve by entering responses and/or updating the data entry fields.

8.2. DQRLs are created according to the DQRL specifications. These are listings on different data point in the EDC and are used to review issues. This and other related specifications serve as a central document to define all data cleaning activities across functional groups.

8.3. "Manual Queries" are entered into the system by BioMarin Study Personnel or designee as a result of data quality review and/or source verification monitoring.

8.4. Query resolution is based on the following:

8.4.1. The CDM is responsible for reviewing and resolving "System Edit Checks" queries programmatically generated within Medidata Rave.

8.4.2. CLO or designee is responsible for reviewing and resolving "CRA to site" queries manually generated by CLO or designee within Medidata Rave as a result of data quality review or source data verification.

8.4.3. The CDM is responsible for reviewing and resolving "DM to site" queries manually generated by Clinical Data Management as a result of data quality review or re-queries.

8.4.4. Queries raised by other study personnel will be reviewed and resolved by the CDM.

8.4.5. A Sites are requested to answer queries within 5 days after issued

9.0 Study Team Communication/Meetings

9.1. The CDM or designee will communicate study status and applicable metrics (as described in Standard Reports and Quality Metrics section) with the appropriate project team members during the following, recurring meetings and ad-hoc as needed and per the DAP and DAP Communication Plan

Meeting Name	Organizer
Ph 3 Study Execution Team (SET) Meeting	Katie MacQuien
Data Working Group	Ann Mikhail
BMRN 270 program weekly meeting (Covance)	Kyle Osborne
270 DM/Clinical System Study Review	Cosmas Collins
270 Study Review/Updates with Offshore	Cosmas Collins
CDM Timeline Update Meeting	Annie Chang
DM Program Lead - DM updates	Ann Mikhail

9.2. Data Working Group

9.3. The Data Working Group is a Data Management-led forum responsible for the successful execution of data management activities. The DWG is primarily responsible for the ongoing monitoring of clinical study data, ensuring quality of data for key efficacy and safety endpoints.

9.4. The DWG reviews upcoming project milestones and plans data cleaning activities to meet the requirements of each deliverable. Any data issues or data handling questions should be addressed during the DWG. In addition, the DWG will include risk management review.

9.4.1.1. Scope of the Data Working Group includes, but is not limited to:

- Data collection and data cleaning planning and design;
- Review of study status metrics, including risk management;
- Resolution of data handling questions;
- Timeline review and milestone planning;
- Review of final study deliverables and status;
- Filing planning, if applicable.

9.4.1.2. Members of the Data Working Group:

- Lead Data Manager
- Clinical Operations Study Team Lead
- Biostatistician
- Statistical Programmer
- Clinical Scientist
- Lead Database Developer
- CRO Team (PSI Team)

<u>Ad-Hoc</u>

- Lead Database Developer
- Local CRAs (or designees) from CRO
- Project Manager
- BPV Sciences Lead
- BPV Operations Lead
- Support DM

- Clinical Programmer
- Clinical Pharmacology Representative
- Immunogenicity Assessment Representative

9.5. Standard Reports and Quality Metrics. The CDM or designee provides data collection and data cleaning metrics to the Data Working Group and highlights trends or issues for team discussion.

9.5.1. eCRF and Query Metrics Report. Medidata Rave-generated report listing eCRFs that are submitted/outstanding/overdue, monitored/unmonitored, as well as outstanding queries (open/answered).

10.0 Medical Coding and Review

10.1. BioMarin Clinical Data Management uses the Medical Dictionary for Regulatory Activities (MedDRA) for Adverse Event, Concomitant Procedures, and Medical History coding, and the WHO Drug Dictionary (WHO Drug) for Medication coding.

10.2. MedDRA Coding Dictionary Version - 20.1

10.2.1. The following CRFs will be coded using the MedDRA dictionary, no up-versioning is planned for this study.

- Medical History
- Adverse Events
- Concomitant Procedures

10.3. WHO Drug Coding Dictionary – HD_DDE_B2-201709

10.3.1. The following CRFs will be coded using the WHO Drug Dictionary, no up versioning is planned for this study.

- Concomitant Medications
- Factor VIII Infusions

10.4. Coding Review. The study CLS lead reviews coding reports generated by the CDM for deliverables, but at the very least quarterly through the life of the study. The CLS lead provides clinical feedback of coding to the CDM. This may take the character of suggesting alternative coding for consistency across study or program, etc. For deliverables that are external to BioMarin, a review and sign off from the Medical Monitor or designee is necessary

A final cumulative coding report is compiled at the end of the study, which the CLS lead is responsible for approving prior to database lock.

11.0 SAE Reconciliation

11.1. Per the Clinical Serious Adverse Event Reconciliation SOP and the Serious Adverse Event Reconciliation Work Instruction, SAE data reported in Rave EDC (CDM) are reconciled with the SAE data reported in Argus.

11.2. SAE Reconciliation for this study is performed based on study deliverable needs, but at a minimum quarterly

11.3. Additional SAE Reconciliation may also be performed in support of snapshots for data analysis, according to the pre-defined parameters approved by the CDM, BPV, CLS, and CLO leads.

11.4. The following fields are reconciled by the data manager:

- Verbatim term
- MedDRA System Organ Class (SOC)
- MedDRA Preferred Term
- Seriousness Criteria
- Severity
- Relationship to Study Drug
- Outcome
- Death
- Onset Date
- Stop Date

11.5. Any discrepancy identified through the SAE reconciliation process is resolved by following the standard query process.

12.0 External Data Transfers

12.1. Data Transfers Received

The following types of data will be received from external sources (other than the eCRF):

Type of Data	Vendor Name	Data Transfer Frequency
IXRS	Almac	Half-way through enrollment and when enrollment is complete.
Laboratory Testing	Covance	As designated in the Data Transfer Specification, (DTS)
Direct Thrombin	BioMarin Analytic Services (BAS)	As designated in the DTS

13.0 Data Monitoring Committee (DMC)

13.1. Quarterly transfers are expected, please refer to DMC charter for more details:

Type of Data	Entity/Vendor Data Exported to	Frequency of data exports
All	DMC	As per the DMC Charter (At least quarterly)

14.0 Local Lab Data

14.1. For lab data received from sources external to BioMarin Clinical Data Management, the units and normal ranges are included as separate variables in the transferred dataset. Collection date and time will not be recorded in the eCRF as this will be part of the data received from the external vendor.

14.2. For local lab results entered directly into EDC, the local labs provide their units and ranges for each lab test. These ranges and units are entered into EDC by the Database Developer.

15.0 Clinical Data Management Study Documentation

15.1. In a timely manner and on an ongoing basis through the lifecycle of the study, the CDM is responsible for filing fully executed, data management-owned essential documents in the eTMF in Veeva Vault.

16.0 Blinding/Unblinding

16.1. This study is not blinded, however a finalized data access plan that references the Data Access, for various role-based data visibility is included in Appendix B.

17.0 Ongoing Analysis of Data Prior to Database Lock

17.1. Snapshot of Ongoing Data. For data analysis purposes including, but not limited to, Data Monitoring Committees (DMCs), publications, etc., the study team defines data snapshot parameters and data quality requirements within the Data Snapshot Request Form. The CDM ensures that the Data Snapshot Request Form is completed and approved by the CDM, BioMarin CLO lead, BioMarin Biostatistician, BioMarin Clinical Programmer (CP), BioMarin Statistical Programmer (SP) and BioMarin CLS lead, as well as the BioMarin BPV lead.

17.2. Once data has been cleaned according to the data snapshot parameters, the CDM or designee communicates to the BioMarin CP that the snapshot is ready to be taken as defined in the Data Snapshot Request Form. The CP copies the database to a controlled/locked ACE activity folder and archives the snapshot data.

18.0 Study Database Pre-Lock Procedures

18.1. Data locks are distinguished from data snapshots such that snapshots are performed on data that are subject to change, while a data lock procedure only applies to unchanging data.

18.2. The CDM documents the planned data lock scope and schedule of activities per SOPs.

18.3. The CDM manages and verifies the data within the scope of the data lock, has been entered, reviewed, and reconciled as necessary, and that all queries against the data have been resolved. In the context of this overall accountability, other study team members also bear function-specific responsibility to ensure data quality in support of the database lock.

19.0 Study Database Lock Procedures

19.1. Once the CDM verifies that all preparations for the data lock are complete, the CDM notifies the study team of the upcoming database lock.

19.2. The CDM and/or BioMarin DD locks all data in the system per the BioMarin SOPs and the CP moves all final external data files into the approved study directories in ACE and sets their file status to "read-only."

19.3. The CDM notifies the study team that the database lock is complete.

20.0 Study Database Unlock and Relock Procedures

20.1. No unlock is planned for this study database at this point.

21.0 Study Close-Out

21.1. Once the Clinical Study Report (CSR) is filed, the BioMarin CDM is responsible for requesting a Master CD and Site CDs from Medidata. The Master CD contains all site/subject clinical data, queries, audit trail, and Protocol Deviations captured within EDC. The Site CD contains all subjects available within that site and associated subject data, queries, audit trail, and Protocol Deviations.

21.2. The BioMarin CDM and BioMarin Clinical Operations lead review the Master CD and Site-specific CD, ensuring all site (master)/subjects are present and that formatting and content are as expected. The CRA lead is responsible for distributing Site CDs for retention at the site. The BioMarin CDM is responsible for filing the Master CD in the BioMarin TMF.

21.3. After all the above database lock and study close-out activities have been completed, the BioMarin CDM is responsible for ensuring that Medidata removes the study from the URL.

22.0 Self-Evidence Corrections (SEC)

22.1. No self-evidence corrections are done on the 270 study. The version 1.0 of the Data Management Plan included a list of previously approved SEC.

23.0 Study-specific Data Handling Decisions

23.1. The following study-specific data handling decisions have been made during the conduct of the study

Date of Documentation	Description of Issue	Data Handling Decision
25AP2019	1: Factor VIII Infusion Form - Subject 1718-4001 - Record numbers 172 and 173 are showing in the EDC as not coded. There was a Coder system issue from Medidata RAVE 2: Subject 1745-4002 was initially screened for 302. This patient fell out of the protocol specific screening window and was rescreened with a new subject ID number 1745-4003. After further consideration, the subject decided that they wanted to enroll in to 270-301 study.	1: Factor VIII Infusion form – Record 172 and 173 will be manually coded by Clinical Programming. 2) CDM has inactivated subject 1745-4002 from the 270-302 EDC. This subject screening data for 1745-4003 originally in 270-302 is now entered and subject is enrolled in study 270-301 under subject ID 1745-3003.
13FEB2020	In the Bloodworks Northwest data transfer file, a subset of the results has incorrect values in their key identifiers, such as subject ID. These errors are due to the site writing an incorrect number on the sample tube label. Bloodworks SOPs require the data in their transfers match what is present on the tube labels, and errors in the data cannot be corrected by Bloodworks.	Please reference note to file. This decision is an update to the original instance of this issue identified on 23SEP2019.

23.2. See SharePoint folder for unresolvable issues, titled “DWG RAID log”: https://bmrn.sharepoint.com/:x:/r/sites/BIO/_layouts/15/Doc.aspx?sourcedoc=%7BEC919D40-3178-4F0A-94AE-C2D6A21BB063%7D&file=270%20Studies%20DWG%20RAID%20LOG%2022Nov19.xlsx&action=default&mobileredirect=true&cid=bb8564c9-cdfe-4fb0-96e0-28539180f9f2

24.0 SOPs referenced for this trial.

DCD-106562	BMT	BMT eCRF Design, Development and UAT Work Instruction	28-Aug-15
DCD-106563	BMT	BMT External Data Transfer Work Instruction	21-Aug-15
DCD-106564	BMT	BMT SAE Reconciliation Work Instruction	21-Aug-15
DCD-108185	BMT	EDC Site Administration Work Instruction	17-Jul-15
DCD-108435	BMT	Data Snapshot Request Work Instruction	21-Aug-15

DCD-108774	BMT	Clinical Study Database Lock, Unlock, and Closeout Work Instruction	18-Sep-15
DCD-108776	BMT	Dictionary Coding of Terms for Clinical Data Work Instruction	18-Sep-15
SOP-103401	BMT	Establishment and Operation of Data Monitoring Committees	27-Apr-15
SOP-103412	BMT	Statistical Program Development	27-Apr-15
SOP-103436	BMT	Study Clinical Database Development & Validation	6-Mar-15
SOP-103680	BMT	Clinical Serious Adverse Event Reconciliation	27-Apr-15
SOP-103863	BMT	Developing Specifications for TLGs and Data Sets	10-Jul-15
SOP-104086	BMT	Development of the Data Management Plan	29-May-17
SOP-104360	BMT	External Data Transfer of Clinical Trial Data	10-Dec-14
SOP-106147	BMT	Unblinding Treatment Codes for Statistical Analysis	28-Jan-15
SOP-107034	BMT	Clinical Study Database Lock, Unlock, and Closeout	22-Apr-15
SOP-107038	BMT	Addressing Discrepancies in Data Snapshots and Locked Databases	22-Apr-15
SOP-108171	BMT	Dictionary Coding of Terms for Clinical Data	28-Aug-15
SOP-115611	BMT	CDM External Data Exchange FTP Servers Clinical Study Folder and User Account Management	30-Jun-17
WI-111313	BMT	Targeted Source Document Verification Setup	12-Jul-16
WI-111315	BMT	CDM Study Document Version Control	11-Jul-16
WI-111553	BMT	Create Activity or Activity-Like Directories in ACE	11-Jul-16
WI-111560	BMT	Rave EDC User Administration	11-Jul-16
WI-111561	BMT	Dictionary Coding Up-versioning and Synonym List Management	11-Jul-16

25.0 Appendix A: Summary of Changes to Study DMP

Version		Affected Section(s)	Summary of Revisions
Number	Date		
1.0	20-FEB-2018		First Version
2.0	26MAR2020	1.0, 3.0, 4.0, 5.0. 6.0, 7.0, 8.0, 10.1, 10.2, 16.1, 17.2, 17.3, 18.0, 19.0, 23.0	Updated all document format Fixed Table of content issues and hyper links Updated signature page with current team members Removed old team members and added the new members to the Data Working Group meetings Clarified responsibilities section Added the ongoing weekly meetings Added the Data Handling Decisions with reference to the approved Note to File. Decision log and permanent issues (Section 23) are added.

26.0 Appendix B: Data Access Plan

Access to and management of the study data will be carried out by following the approved Data Access Plan (DAP) located in the eTMF in Veeva Vault.