

Center For Experimental Therapeutics
School of Medicine
University of Pennsylvania Health System
654 BRB II/III
421 Curie Blvd
Philadelphia, PA 19104
TEL: 215-573-4176
FAX: 215-573-8606

MEMORANDUM

To: Data Safety Monitoring Board Members
Peter Adamson, MD (Chair)
Roger Illingworth, MD
Frederick Nunes, MD

From: Daniel J. Rader, MD

Date: February 9, 2004

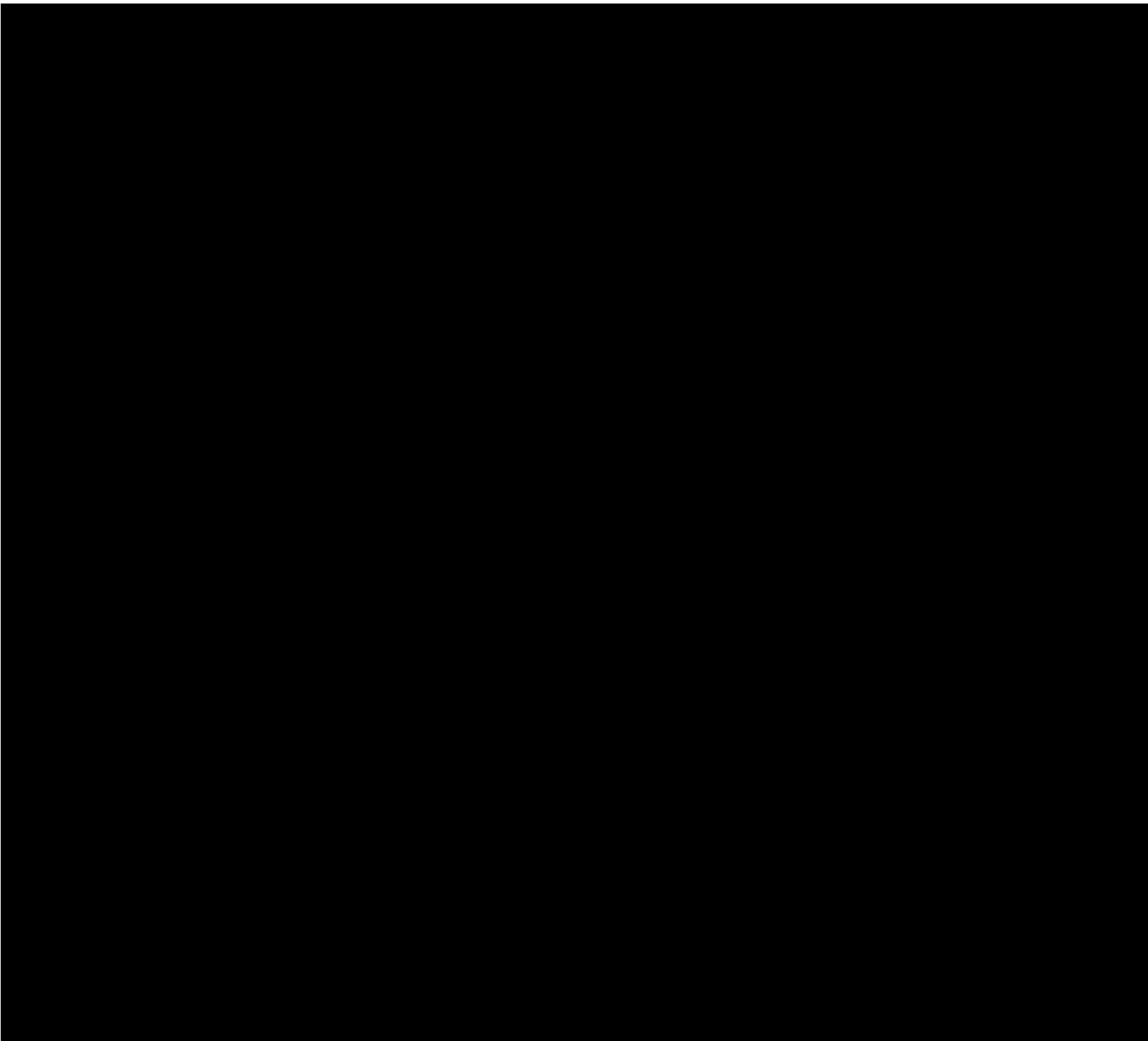
Re: Data from 6 enrolled patients

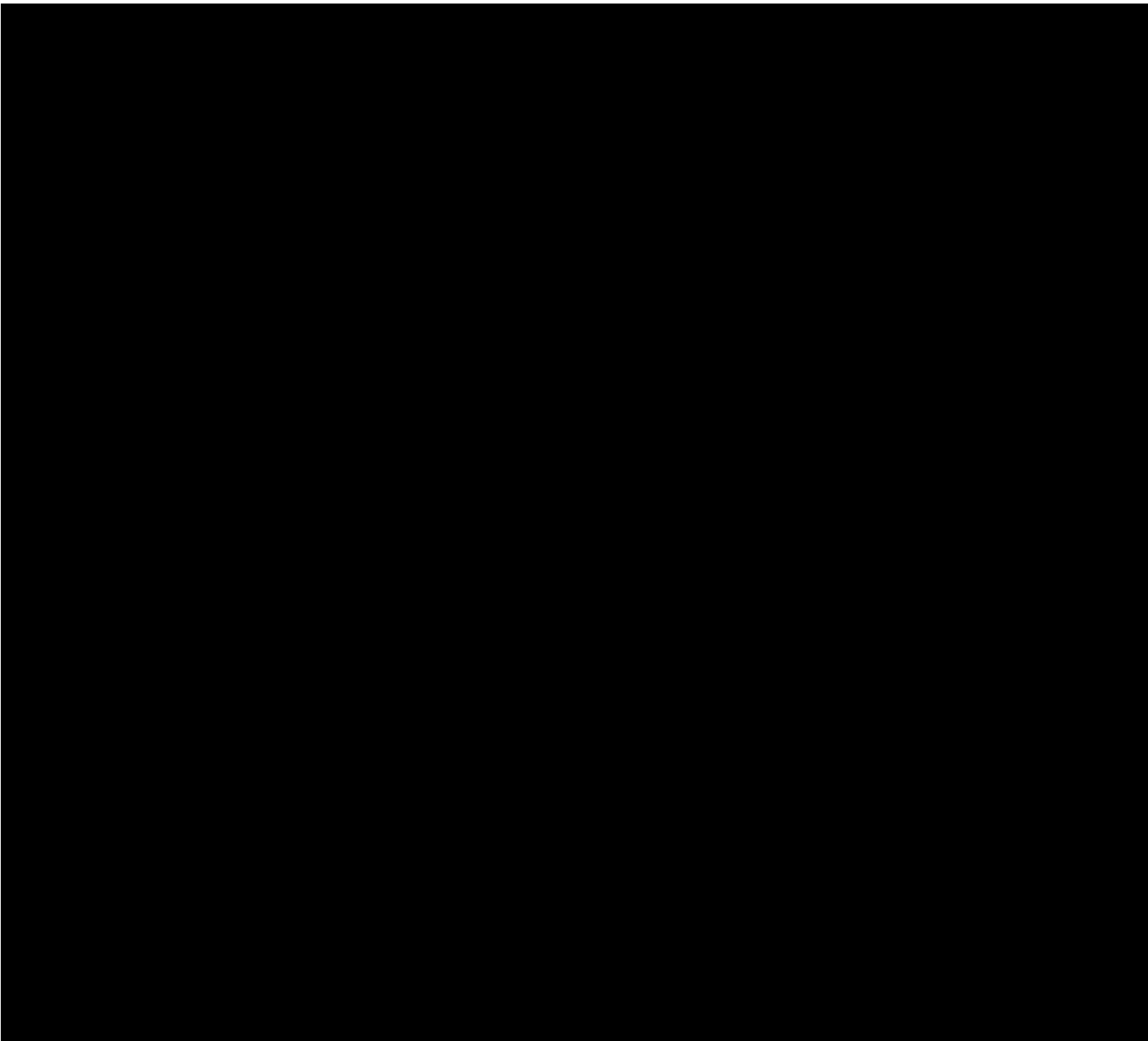
Title: **A Phase II Open Label, Dose-Escalation Study to Determine the Safety, Tolerability and Efficacy of Microsomal Triglyceride Transfer Protein (MTP) Inhibitor BMS-201038 in Patients with Homozygous Familial Hypercholesterolemia (Protocol No. UP 1001)**

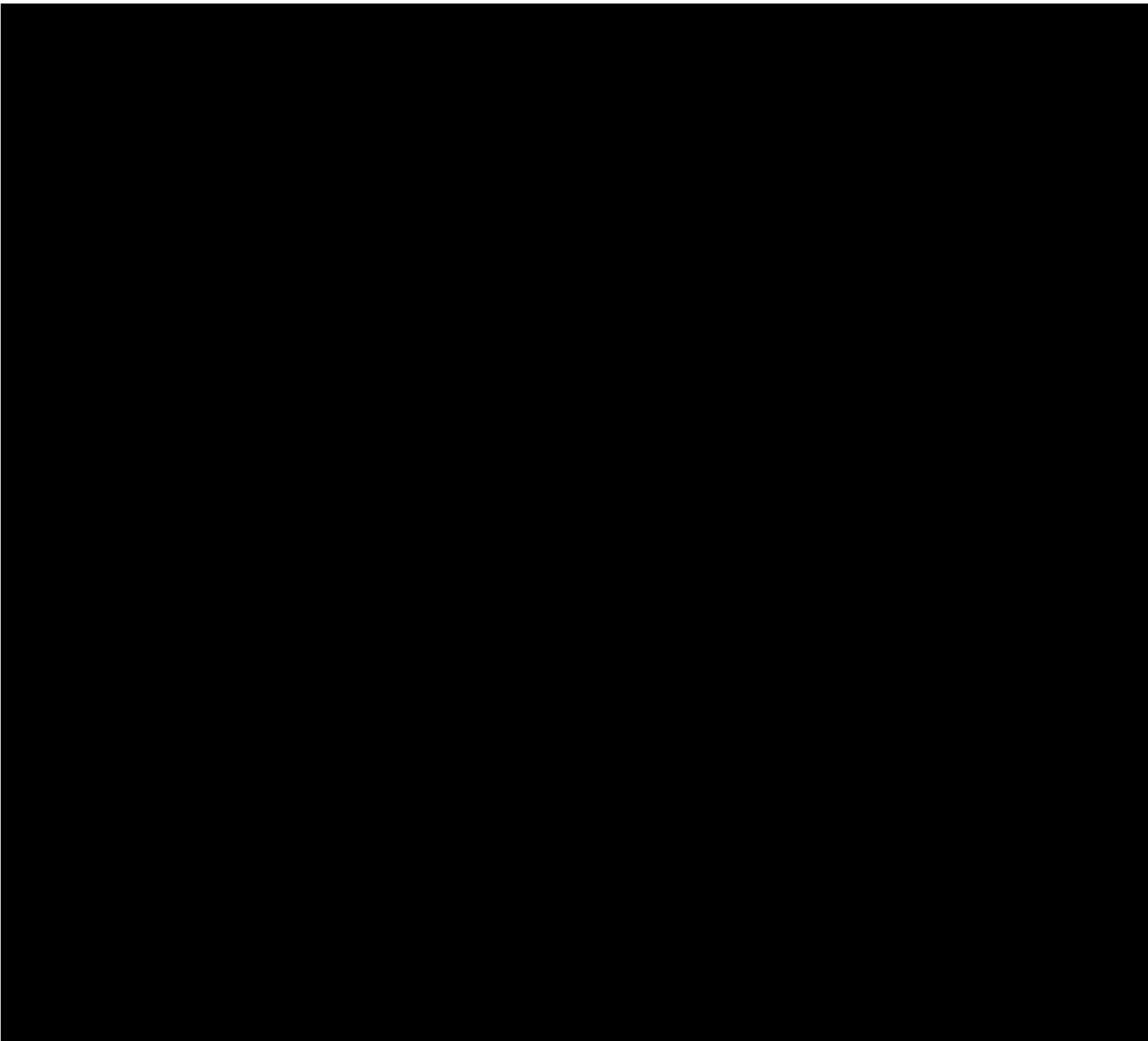
Please find enclosed the following appendices describing the available clinical data of 6 patients enrolled in the above reference protocol.

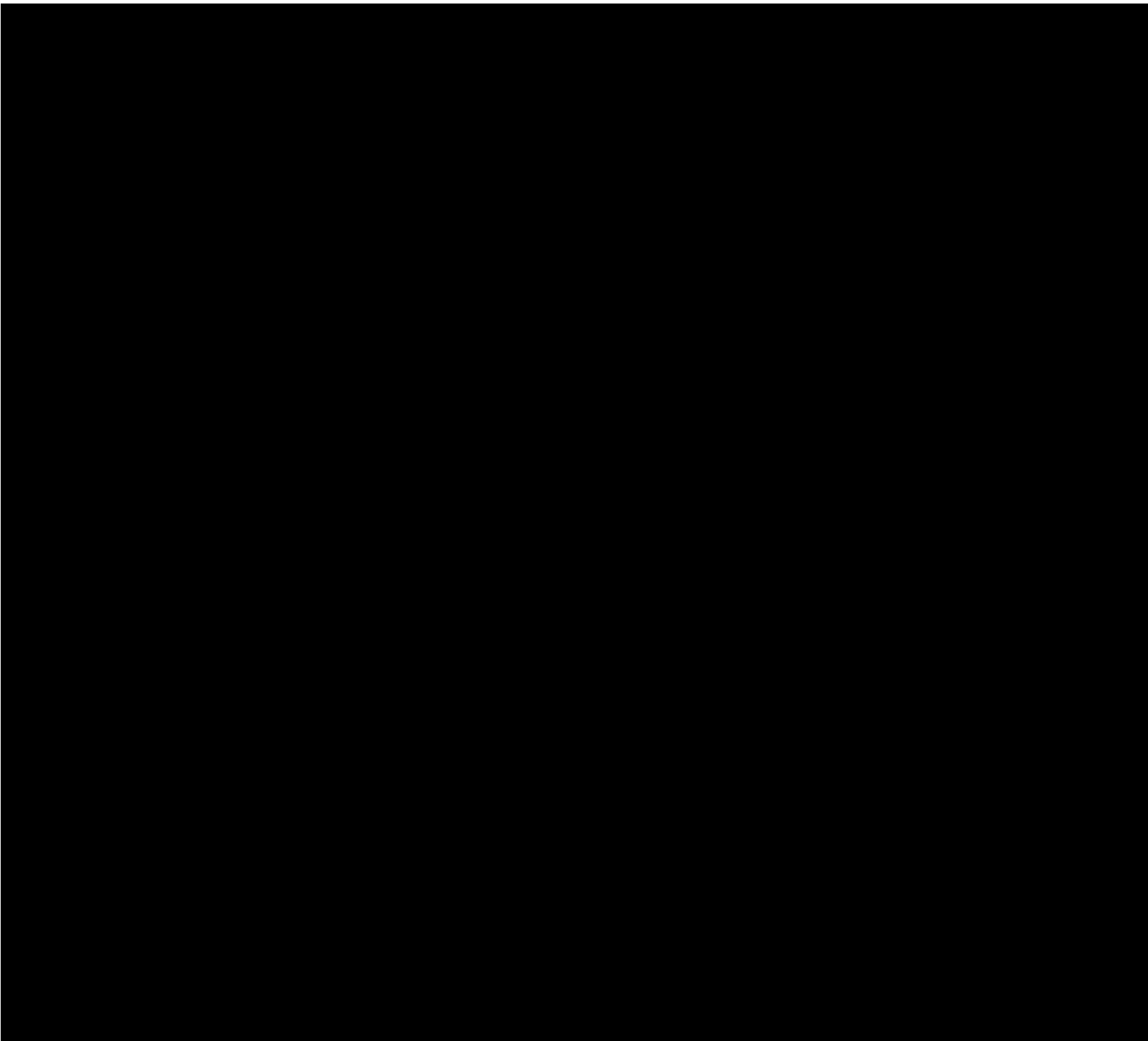
Appendix 1: Subject Demography at Baseline
Appendix 2: Extent of Exposure to Study Drug BMS-201038
Appendix 3: Vital Signs Listing
Appendix 4: Pulmonary Function Tests and NMRS/MRI of the Liver by Subject
Appendix 5: Listing of Adverse Events by Subject
Listing of All Reported Clinical and Laboratory Adverse Events
Appendix 6: Listing of Adverse Events by Event
Listing of All Reported Clinical and Laboratory Adverse Events
Appendix 7: Listing of Laboratory Parameters by Subject
Appendix 8: Percent Change in Total Cholesterol at the End of Each Treatment Dose Compared to Baseline
Appendix 9: Percent Change in Non-HDL Cholesterol at the End of Each Treatment Dose Compared to Baseline
Appendix 10: Percent Change in Apolipoprotein B at the End of Each Treatment Dose Compared to Baseline
Appendix 11: Fat Soluble Vitamins and Fatty Acid Profile in Subjects Receiving BMS-201038

Please do not hesitate to contact me if you have any questions or require additional information. We thank you for your time in serving on the DSMB for this study and are excited by the efficacy and reasonable tolerability of this MTP inhibitor compound in these homozygous FH patients.









Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.