

Diabetes Autoimmunity Study in the Young (DAISY)

Children determined to be at an increased risk for development of type 1 diabetes (T1D), either due to known genetic markers or due to family history of T1D, are followed from birth and monitored on an annual basis for development of T1D-related autoimmunity. At annual clinic visits, participants are tested for development of these autoantibodies and data are collected related to environmental exposures. In addition to blood collection for determination of autoantibodies, serum and plasma are frozen and stored for future analyses, along with other biological samples such as throat swabs, rectal swabs, saliva, and urine. If T1D-related autoantibodies are detected, the participant is asked to increase the frequency of clinic visits to 2-4 visits per year in order to monitor for the onset of disease more closely. The endpoint of the study is diagnosis of T1D per the American Diabetes Association (ADA) criteria.

Archive files are organized into the following directories:

- Data
- Documents
- Dataset Integrity Check (DSIC)
- Forms

Data

The Data directory contains the following files:

- SUBJECTLEVELDATA.CSV
- subjectleveldata.sas7bdat
- VISITLEVELDATA.CSV
- visitleveldata.sas7bdat

Data/Contents

- DAISY IBMWatsonDataDictionary_updt_12_2020.xlsx

Documents

The DAISY Documents directory contains:

- DAISY 2020 Research Strategy_R01 DK032493-37.pdf
- DAISY_Protocol.pdf
- DAISY_Protocol_Summary.pdf

Documents/DAISY MOO

- DAISY Study Manual of Operations_Table of Contents.pdf

Documents/DAISY MOO/A-Screening/Forms

- A-ScreeningConsent2001clean.pdf
- B-ScreeningHIPAA.pdf
- C-ExemplaHIPAAformforscreening.pdf
- D-NecScreenrevisedJun04.pdf
- E-DAISY Screening Tracking Form_June 2004.xls

- F-Cover Letter for Pendings.pdf
- G-List of Autoimmune Disease.pdf
- H-ONE-THIRD YELLOW SHEETS.pdf

Documents/DAISY MOO/A-Screening/Procedures

- A-ScreeningCordBloodCollection5_04.pdf
- B-ScreeningRecruitment5_04.pdf
- C-ScreeningLab_CordBloodProcessing.pdf
- D-DAISY Screening Recruiter Checklist.pdf
- E-Pending Cord Blood protocol.pdf
- F-Refusal_Ineligible Reasons.pdf
- G-High Priority Roche Testing.pdf
- H-ScreeningDataManagement5_00.pdf
- ScreeningSummary.pdf

Documents/DAISY MOO/B-HLA Typing/Appendix

- A-RocheProbe.pdf
- B-ProbePattern2000.JPG
- C-ShipList.pdf
- D-ROCHE QC Template.pdf
- E-RocheResendsTemplate.pdf
- F-ImportingPrinting Roche Results.pdf
- G-RocheResultsLetters_QueriesToPrint.pdf
- H-FamLetter.pdf
- I-GenPopNoTypeLetter.pdf
- J-UnableToContactLetter.pdf
- K-BabySocHLAHighRiskLetter.pdf
- L-BabySocHLALowRiskLetter.pdf
- M-NocNoTypeLetter.pdf

Documents/DAISY MOO/B-HLA Typing/Procedures

- A-RocheShipping.pdf
- B-RocheImport.pdf
- C-RocheQC.pdf
- D-RocheResends.pdf
- RocheSummary.pdf

Documents/DAISY MOO/C-NEC Surveillance/Appendix

- A-SurveillanceLtr.pdf

Documents/DAISY MOO/C-NEC Surveillance/Procedures

- A-NecFollowMailing.pdf
- B-NecFollowDataEntry.pdf
- C-NecFollow.pdf
- NecSurveillanceSummary.pdf

Documents/DAISY MOO/D-Enrollment/Appendix

- A-MedRelease.pdf
- B-famenrol.pdf
- C-DisenrollmentForm2002.pdf
- D-Re-enrollment-halfpad.pdf
- E-FollowUpHIPAA.pdf
- F-NEC_Ind.pdf
- G-SOC_Ind.pdf
- H-B Letter - Disenroll.pdf
- ROCHE Confirmation send form.pdf

Documents/DAISY MOO/D-Enrollment/Procedures

- A-NOTIFICATION OF RESULTS AND ENROLLMENT OF NEC.pdf
- B-EnrollmentContact_FAQ.pdf
- C_EnrollmentDecline.pdf
- D-EnrollmentAccept.pdf
- E-EnrollmentRocheConfirmation.pdf
- F-EnrollmentCBAntibodies.pdf
- G-EnrollmentDataEntry.pdf
- H-Enrollment34Sibs.pdf
- I-Disenrollment.pdf
- J-Reenrollment.pdf
- K-DisenrollDataEntry.pdf
- Summary_Enrollment.pdf

Documents/DAISY MOO/E-Pregnancy and Infancy FormTrack/Appendix

- NEC_Ind.pdf
- SOC_Ind.pdf

Documents/DAISY MOO/E-Pregnancy and Infancy FormTrack/Procedures

- A_PandIFormTracking.pdf
- B_PandIFormEditing.pdf
- C_PandIFormDataEntry.pdf
- PandIFormSummary.pdf

Documents/DAISY MOO/F-Scheduling/Appendix

- 2_DAISY Mass Scheduling Timeline.pptx
- Access Database MOO.pdf
- DAISY Scheduling_Confirmation Script email_text.pdf
- DAISY_GENERIC OFFSITE VISIT PACKET LETTER.pdf
- OGTT Instructions.pdf
- OGTT Scheduling Script_phone.pdf
- Recontact Letter 92-080.pdf
- Recontact Questionnaire 92-080.pdf
- Scheduling Postcard Template.pdf

- Scheduling Scripts_phone.pdf

Documents/DAISY MOO/F-Scheduling/Procedures

- A-DAISY Mass Scheduling Protocol.pdf
- B-DAISY Map - to e-mail.pdf
- C-DAISY Scheduling_Add ClinicTrack.pdf
- D-DAISY Scheduling_AppointmentLimits Guidelines.pdf
- E-DAISY Scheduling_Confirmation Emails MOO.pdf
- F-DAISY Scheduling_DataEntry Offsites Rescheduling.pdf
- G-DAISY Scheduling_OGTT Visits.pdf
- H-DAISY Scheduling_Reminder Postcards.pdf
- I-DAISY Scheduling_Updating Enrollment Status.pdf
- J-DRAFT_DAISY Visit Confirmation Procedure.pdf
- K-Scheduling Attempts Overview.pdf
- L-Scheduling notes for clinicians.pdf
- Summary_DAISY Scheduling.pdf

Documents/DAISY MOO/G-Interviews/Appendix

- 3-15Interviewing Tips.pdf
- 3-15Rev7-02.pdf
- AnnualUpdateScanableRev 03_2015_rev2.pdf
- AnnualUpdateScanableRev11-09.pdf
- BabySOC3-15 Nov12_2002.pdf
- BabySOCInterview.pdf
- Conducting 3-15's.pdf
- NEC_Individual_1995.pdf
- Other Diabetes Diagnosis Questions.pdf
- SocIndivSup.pdf
- SOC_Individual.pdf
- Supplemental Activity questionnaire.pdf
- SuppSoc_Indv_vit.pdf

Documents/DAISY MOO/G-Interviews/Procedures

- A-CallSheet.pdf
- B-InterviewClinic.pdf
- C-InterviewsPhone.pdf
- D-InterviewTracking.pdf
- E-Int3-15.pdf
- F-IntAnnual.pdf
- G-Edit3-15.pdf
- H-EditAnnual.pdf
- I-DataEntry.pdf
- J-Other Diabetes Questionnaire.pdf
- Summary_Interviews.pdf

Documents/DAISY MOO/H-Immunizations/Appendix

- HIPAAformForImmunizations.pdf

Documents/DAISY MOO/H-Immunizations/Procedures

- A-ImmunizationData_ObtainingHIPAAForm.pdf
- B-ImmunizationDataHCP.pdf
- C-ImmunizationDataFaxHIPAAForm.pdf
- D-ImmunizationsDataEntry.pdf
- Immunization Data Collection.pdf

Documents/DAISY MOO/I-Clinic Visit/Appendix

- AdverseEventReport.pdf
- AnnualUpdateScanableRev 03_2015_rev2.pdf
- ANTHROPOMETRY measurements for DAISY subjects.pdf
- Autoimmune Diseases List.pdf
- Blood Glucose Testing.pdf
- BloodAllocation_update Jan2020.pdf
- CEDARSX&24hrVitQuestions.pdf
- ClinicVisitForm.pdf
- DAISY Appreciation Gift MOO_092016.pdf
- DAISY Re-Engagement Visit MOO.pdf
- DiseaseStatusUpdate.pdf
- LTF or Surveillance Clinic Visit MOO.pdf
- OtherDiabeteDxQuest_MH3.8.18.pdf
- Positive Illness Update Form.pdf
- Supplemental Activity questionnaire.pdf
- Tanner - Female.pdf
- Tanner - Male.pdf
- Tanner Cover Letter.pdf

Documents/DAISY MOO/I-Clinic Visit/Procedures

- A-ClinVisPrep.pdf
- B-ClinVisInitialInteractions.pdf
- C-ClinVisPaperwork.pdf
- D-MissingData.pdf
- E-ClinVisBioSamples.pdf
- F-Addnl DNA 09_2008.pdf
- G-BIA Measurement Using TANITA Body Composition Device.pdf
- H-DAISY Supplemental Activity questionnaire MOO.pdf
- I-Other Diabetes Questionnaire procedure.pdf
- J-Daily Chart Preparation MOO_updt 062019.pdf
- SummaryClinicVisit.pdf

Documents/DAISY MOO/J-Long Distance Protocols/DAISY LDP

- A-DAISY LDP MOO.pdf

- B-DAISY_Long Distance Protocol_Req of Service.pdf
- C-DAISY LDP Blood Kit Supply List.pdf
- D-DAISY LDP Interview MOO.pdf
- E-LDP MOO for lab staff.pdf

Documents/DAISY MOO/J-Long Distance Protocols/FingerPoke Protocol

- A-DAISY COVID FingerPoke Protocol_08282020.pdf
- B-Annual Interview and Finger Poke Protocol Kit Procedure_09032020.pdf
- C-DAISY Finger Poke LDP Specimen Collection Form 08_2020.pdf
- D-W9 Form_2018.pdf

Documents/DAISY MOO/K-Specimen Processing Lab/Appendix

- A-DAISYLabtray_AbNeg.xls
- B-DAISYLabtray_AbPos.xls
- C-TubeAliquotDAISY.pdf
- D-TubeAliquotIVY.pdf
- E-ClinicVisist_SampleTrackingSheet.pdf
- F-Tracking sheet for DM AB's and TGIgA.xls
- G-mRNATracking.pdf
- H-Collection of Serum for TGIgA Testing.pdf
- I-ConsentFormApprovalSampleCollection.pdf
- J-RocheBatchQC.pdf

Documents/DAISY MOO/K-Specimen Processing Lab/Procedures

- A-LabSamplesToCollect.pdf
- B-LabBloodProcessing1_2015.pdf
- B-LabBloodProcessing2_2015.pdf
- C-DAISY Clinic Visit-Blood Sample Processing 06_20.pdf
- D-LabBarcodes.pdf
- E-DAISY Clinic Visit-DNA to BDC Sample Processing 06_20.pdf
- F-DAISY Clinic Visit-LDP Blood Sample Processing.pdf
- G-DAISY LDP Blood Kit Data Entry 06_20.pdf
- H-DAISY Very Short Draw Priority.pdf
- I-Finger Poke LDP Protocol.pdf
- J-LabPaperwork.pdf
- K-LabDataEntry_web database.pdf
- L-LabSendToBdcAbLab.pdf
- M-LabQcProcedure_updt.pdf
- N-Urine Glucose_Ketone.pdf
- O-Starting a New Roche Box.pdf
- P-High Priority Roche Testing.pdf
- Q-DAISY Processing FAQ 06_20.pdf
- Summary_LAB.pdf

Documents/DAISY MOO/L-Surveillance Tracking/Appendix

- DAISY Surveillance Letter Oct 1 2018_92-080.pdf
- DAISY Surveillance Letter Oct 1 2018_FINAL.pdf
- DAISY Surveillance Questionnaire 92-080_Oct 2018.pdf
- DAISY Surveillance TrackingMarch 2018.pdf
- LTF Postcard_2016.pdf

Documents/DAISY MOO/L-Surveillance Tracking/Procedures

- A-DAISYFollowMailing.pdf
- B-DAISYFollowDataEntry.pdf
- DAISYSurveillanceSummary.pdf

Documents/DAISY MOO/M-DAISY OGTT/Appendix

- A-DAISY OGTT clinic worksheet.pdf
- B-OGTT Lab sample worksheet_DAISY.pdf
- C-OGTT lab labels.pdf
- D-CHC 804 Core lab req.pdf
- E-OGTT Lab Sample Tracking_Template.xlsx
- OGTT results letter diabetes.pdf
- OGTT results letter impaired.pdf
- OGTT results letter normal.pdf

Documents/DAISY MOO/M-DAISY OGTT/Procedures

- A-OGTT instructions DAISY 2015.pdf
- B-MOO DAISY OGTT.pdf
- C-DAISY OGTT Laboratory Procedures 07_2015.pdf

Documents/DAISY MOO/N-Diagnosis/Procedures

- Daisy Dx_data management.pdf

Documents/DAISY MOO/O-Antibody Testing

- Islet Autoantibody Testing.pdf

Documents/DAISY MOO/P-Antibody Results Reporting/Appendix

- A-Positive Followup.pdf
- B-REQUEST FOR BDC QC.pdf
- C-QcSent.pdf
- D-AntibodyPosCutoff.pdf
- E-DAISY PosClass Codes.pdf
- G-TrackingSend sheet for DM AB's and TGlgA.xls
- H-Notation To Parents-Harmonized Assay.pdf

Documents/DAISY MOO/P-Antibody Results Reporting/Appendix/Results Letters/AB Letters 2012

- AB Letter Inconclusive.pdf
- AB Letter Negative Parent.pdf

- AB Letter Negative Previously Positive Parent.pdf
- AB Letter Negative Previously Positive.pdf
- AB Letter Negative Sibling.pdf
- AB Letter Negative Study Subjects Over 18.pdf
- AB Letter Negative Study Subjects.pdf
- AB Letter Positive 1AB Continued Parents.pdf
- AB Letter Positive 1AB Continued.pdf
- AB Letter Positive 1AB Over 18.pdf
- AB Letter Positive 1AB Parent.pdf
- AB Letter Positive 1AB.pdf
- AB Letter Positive 2+ Parent.pdf
- AB Letter Positive 2+.pdf
- AB Letter Repeatedly Negative Previously Positive.pdf

Documents/DAISY MOO/P-Antibody Results Reporting/Appendix/Results Letters/AB Letters Revised 2019

- 92-080 AB Letter Positive 1AB 06_26_19.pdf
- 92-080 AB Letter Positive 1AB Over 18 06_26_19.pdf
- 92-080 AB Letter Positive 1AB Persistent 06_26_19.pdf
- 92-080 AB Letter Positive 2+ 06_26_19.pdf
- 92-080 AB Letter Positive 2+AB over 18 06-26_19.pdf

Documents/DAISY MOO/P-Antibody Results Reporting/Procedures

- 1-AntibodySummary.pdf
- A-AntibodyImport.pdf
- B-AntibodyNotification.pdf
- C-AntibodyPositiveFup.pdf
- D-AntibodyResultNotification.pdf
- E-Instructions for Parents.pdf

DSIC

The DAISY Dataset Integrity Check (DSIC) directory contains:

- DAISY_DSIC.pdf

Forms

The DAISY Forms directory contains:

- AnnualUpdateScanableRev 03_2015_rev2.pdf
- AnnualUpdateScanableRev11-09.pdf
- CEDARSX&24hrVitQuestions.pdf
- ClinicVisitForm.pdf
- DiseaseStatusUpdate.pdf
- Famenrol.pdf
- List of Autoimmune Disease.pdf

- NecScreen.pdf
- NecScreenrevisedJun04.pdf
- OtherDiabeteDxQuest_2018.pdf
- SocIndivSup.pdf
- SOC_Individual.pdf
- Supplemental Activity questionnaire.pdf
- Tanner_puberty female 04-11-06.pdf
- Tanner_puberty male 04-11-06.pdf
- Update3-15 Quest Rev7-02.pdf