R100: Eligibility Screening:

|  |  |  |
| --- | --- | --- |
| Field name | description | value |
| Blind\_id | PK |  |
| screen\_age | Age at start screening (days) |  |
| Gender | Gender (1 male,2 female) |  |
| Race | Race (8 values) |  |
| HISPANIC | Is hispanic (yes 1, no 0) |  |
| BWT | Birth weight |  |
| lowbwt | Birth weight <2500g, (yes 1, no 0) |  |
| GESTAGE | Gestational age, weeks |  |
| preterm | (yes 1, no 0) |  |
| bwtgrp | Bwt for age group (1,2,3) |  |
| PRENATDX | Prenatal diagnosis of congenital heart disease |  |
| FET ALINT | Fetal intervention |  |
| adx | Anatomic Diagnosis Code |  |
| ASSOCDX | Any associated anatomic diagnoses? |  |
| ATRESIA | Does patient have aortic atresia? |  |
| BSTRUCT | Does patient have obstructed pulmonary venous return? |  |
| HLHS | Does patient have hypoplastic left heart syndrome |  |
| CONGENTL | Does patient have any major congenital abnormality |  |
| HERNIA | Congenital diaphragmatic hernia |  |
| FISTULA | Tracheoesophageal fistula |  |
| NEEDV ANT | Need for high frequency ventilation |  |
| RENAL | Renal failure requiring dialysis |  |
| TRISOM13 | Trisomy 13 | genetic |
| TRISOM18 | Trisomy 18 | genetic |
| NOSHUNT | Any preoperative anatomic evidence |  |

R102: Pre-Norwood Medical History

|  |  |  |
| --- | --- | --- |
| Field name | description | value |
| Blind\_id |  |  |
| APGAR1 | APGAR score at 1 min | How well did the child did after birth |
| APGAR5 | APGAR score at 5 min |  |
| HIGHLACT | Highest lactate, mmol/L |  |
| INTUB\_R | Reason for intubation, 7 values | Good for LOV |
| GASCO2 | Inhales gases CO2 |  |
| GASN2 | Inhales gases N2 | Lung needs support (LOV) |
| BNUMCATH | Number of cardiac catheterization prior to norwood | Used for diagnosis for anatomy hemodynamics complex |
| CARDINT | Cardiac operative interventions performed | 1 yes, 0 no |
| ATRSEP | Atrial septectomy (yes,no) |  |
| atrsep\_age | Age at atrial septectomy (days) |  |
| BALLOON | Left atrial decompression: Balloon (yes,no) |  |
| Balloon\_age | Age at Balloon |  |
| STENT | Left atrial decompression: Stent (yes,no) |  |
| Stent\_age | Age at stent |  |
| PABAND | Bilateral PA banding (yes,no) |  |
| paband\_age | Age at paband |  |
| BNUMSURG | Number of other surgical procedures |  |
| CPB | Number of above procedures for which patient was placed on cardiopulmonary bypass |  |
| CPB\_MN\_0 | Bypass time |  |
| DHCA\_YN\_0 | DHCA (yes,no) | Brain perfusion? |
| DHCA\_MN\_0 | DHCA minutes | Good predictor |
| RCP\_YN\_0 | RCP (yes,no) |  |
| RCP\_MN\_0 | RCP minutes |  |
| bcompcode | Concatenation of all pre-Norwood complication codes |  |

R103: Norwood hospitalization

|  |  |  |
| --- | --- | --- |
| Field name | description | value |
| Blind\_id | PK |  |
| nor\_age | Age at Norwood | days |
| trt | Shunt type | 1: MBTS  2: RVPAS |
| ctrt | Shunt type at the end of Norwood operation | 1: MBTS  2: RVPAS |
| nordis\_age | Age at Norwood hospital discharge | days |
| CCLAMP\_T | Total cross clamp time | minutes |
| BYPASS | Was patient put on bypass | 1: yes  2: no |
| BYP ASS\_T | Total bypass time | minutes |
| DHCA | Deep hypothermic circulatory arrest | 1: yes  2: no |
| DHCA\_T | Total deep hypothermic circulatory arrest time | minutes |
| RCP | Regional cerebral perfusion | 1: yes  2: no |
| RCP\_T | Regional cerebral perfusion time | minutes |
| newrcpdhca |  | 1: DHCA only  2: RCP only  3: both |
| LOWTEMP | Lowest temperature obtained during bypass | C |
| LOW\_HCT | Lowest HCT | % |
| STEROIDS | Steroids | 1: yes  2: no |
| TRASYLOL | Trasylol (Aprotinin) | 1: yes  2: no |
| ABLOCK | Alpha blockade | 1: yes  2: no |
| ASCAORT A | Exterior diameter ascending aorta | mm |
| NTAPVC | TAPVC | 1: yes  2: no |
| NT APTYP | TAPVC: Type | 2,3,4,5 |
| NPAPVC | PAPVC | 1: yes  2: no |
| TYPEARCHR | Type of arch reconstruction | 1: classic  2: direct |
| SHUNTRND | Shunt to which patient randomized | 1: MBTS  2: RVPA |
| SHNTMBTS | At conclusion of Norwood surgery, did patient receive MBTS | 1: yes  2: no |
| SHNTRVP A | At conclusion of surgery, did patient receive RV-to-PA? | 1: yes  2: no |
| CROSSOVR | At conclusion of surgery, did patient receive the assign shunt or both shunts? | 1: yes  2: no |
| NOTHPROC | Were other procedures done at time of Norwood procedure? | 1: yes  2: no |
| reticu\_age | Age at date of return to ICU | days |
| ICUDAYS | Total days of ICU stay | days |
| NEXTUBOR | Was patient extubated in the OR? | 1: yes  2: no |
| NVENTDA YS | Total days ventilated | days |
| PNECMO | Placed on ECMO? | 1: yes  2: no |
| PNCPR | CPR? | 1: yes  2: no |
| NNUMCATH | Number of interventional cardiac catheterizations |  |
| NNUMSURG | Number of other surgical procedures |  |
| NNUMCOMP | Number of significant complications after Norwood |  |
| NNUMMED | Number of discharge medications |  |
| NO2SAT | Oxygen saturation at discharge | % |

R104: Stage II Hospitalization

|  |  |  |
| --- | --- | --- |
| R104\_age | Age at date of form completion | days |
| PCPB | Number of procedures with cardiopulmonary bypass |  |
| PPACER | Pacemaker placed | 1: yes  2: no |
| SANATDX | Number of significant anatomic diagnoses |  |
| STG2\_age | Age at date of stage II procedure | days |
| St2\_los | Length of stage II hospitalization | days |
| SBYPASS | Was patient put on bypass | 1: yes  2: no |
| SBYP ASS\_T | Total bypass time | minutes |
| SDHCA | DHCA | 1: yes  2: no |
| SDHCA\_T | Total DHCA time | minutes |
| SRCP | Regional Cerebral Perfusion | 1: yes  2: no |
| SRCP\_T | RCP time | minutes |
| SLOWTEMP | Lowest temperature obtained during bypass | C |
| SHCT | HCT | % |
| SNECMO | ECMO | 1: yes  2: no |
| ICUDAYS | Total days of ICU stay | days |
| POSTEXOR | Was patient extubated in the OR | 1: yes  2: no |
| POSTVENTDA YS | Total days ventilated | days |
| POSTCPB | Number of procedures with cadiopulm. bypass |  |
| POSTP ACER | Pacemaker placed | 1: yes  2: no |
| SO2SAT | Oxygen saturation at discharge | % |

R105: Stage II Medical History

|  |  |  |
| --- | --- | --- |
| CATHNO | Number of interventional cardiac catheterizations |  |
| cathcod | Concatenation of all catheterization codes |  |
| NUMSURG | Number of other surgical interventions |  |
| CPB | Number of above procedures for which patient was placed on cardiopulmonary bypass |  |
| PACER | Pace maker placed? | 1: yes  2: no |
| ARRHYTH | Arrhythmia requiring medication or intervention? | 1: yes  2: no |

R106: Clinical Genetics Evaluation

|  |  |  |
| --- | --- | --- |
| Geval\_age | Age at the date of evaluation | days |
| HT\_GEVAL | length | cm |
| GEVAL\_haz\_who | Length/height-for-age-z-score |  |
| WT\_GEVAL | weight | kg |
| GEVAL\_waz\_who | Weight-for-age z-score |  |
| SYNDROM | Does patient have an identifiable syndrome | 1: yes  2: no |
| SYNDROME | Does patient have an identifiable syndrome: code |  |
| ABNORM | Were there any abnormalities detected | 1: yes  2: no |

R107: Cardiac Catheterization

|  |  |  |
| --- | --- | --- |
| R107\_age | Age at the completion | days |
| CATH\_YN | Was a cardiac catheterization completed for this patient | 1: yes  2: no |
| BSA\_CA TH | Body surface area | m2 |
| SEDATION | sedation | 1: general anesthesia  2: moderate sedation |
| SVP | Systolic ventricular pressure | mmHg |
| EDVP | End diastolic ventricular pressure | mmHg |
| SAP | Systolic aortic pressure | mmHg |
| DAP | Diastolic aortic pressure | mmHg |
| MAP | Mean aortic pressure | mmHg |
| MPAP | Mean pulmonary artery pressure | mmHg |
| RPAP | Right pulmonary artery pressure | mmHg |
| LPAP | Left pulmonary artery pressure | mmHg |
| RPVP\_CWP | Right pulmonary venous pressure or capillary wedge pressure | mmHg |
| LPVP\_CWP | Left pulmonary venous pressure or capillary wedge pressure | mmHg |
| MSVAP | Mean systemic venous atrial pressure | mmHg |
| OXYG\_SUPPL | Supplemental oxygen during catheterization | 1: yes  2: no |
| OXYG\_MODE | Supplemental oxygen mode of delivery | 1: positive pressure  2: face mask |
| AORT\_SAT | Aortic saturation | % |
| PAS | Pulmonary artery saturation | % |
| SVC\_SAT | SVC saturation | % |
| PV\_SAT | PV saturation | % |
| PULMSYSRAT | Pulmonary to systemic flow ration |  |
| PV\_RESIST | Pulmonary vascular resistance | Wood units |
| PA\_ANGIO | Was an angiogram performed | 1: yes  2: no |

R108: Primary outcome

|  |  |  |
| --- | --- | --- |
| FOLLOWUP | Follow up | 1: prior to 12 month  2: 12 month  3: prior to end of trial |
| TYPEPT | Type of patient | 1: randomized  2: observation |
| OUTVITAL | status | 1: alive  2: dead  3: lost to follow-up |
| DEA THSVR | Was death related to SV diagnosis or surgery? | 1: yes  2: no |
| HTYNLIST | Heart transplant status | 1: no transplant  2: listed for transplant  3: Transplanted |

R113: Functional Status II

|  |  |  |
| --- | --- | --- |
| HOSPITAL | Has your child been hospitalized in the last 6 months | 1: yes  2: no |
| HOSPDAYS | For how many days was he/she hospitalized | Days |
| INCOME | Which best describes the combined income for your household | 7 groups |
| totalall | Total score for all age | Out of 100 |
| total | Total score for 1<2 | Out of 100 |
| genhealth | General health for 1<2 | Out of 100 |
| response | Responsiveness | Out of 100 |

R114: Bayley Scoring Summary

|  |  |  |
| --- | --- | --- |
| MENTRAW | Mental Scale raw score |  |
| MDISCORE | MDI Score |  |
| MOTORRAW | Motor Scale raw score |  |
| PDISCORE | PDI Score |  |
| ORNTPERC | Orientation / Engagement: Percentile |  |
| EMOTPERC | Emotional Regulation: Percentile |  |
| MOTPERC | Motor Quality: Percentile |  |
| TOTPERC | Total Score: Percentile |  |

R114: Socioeconomic Status

|  |  |  |
| --- | --- | --- |
| Country | Country | 1: US  2: Canada  3: other |
| STATE | state |  |
| MED\_INSUR | Does the subject have medical insurance? | 1: yes  2: no |
| STATE\_14 | State or Province of Residence |  |

R206: Between Visit Complication

|  |  |  |
| --- | --- | --- |
| VISITINT | Study visit |  |
| R206\_age | Age at the visit | days |
| BNUMCOMP | Number of significant complications |  |
| bcompcode | Concatenation of all complications code |  |
| B\_comp\_age\_0 | Age at date of complication onset | days |

R300: Clinical Assessment at the time of Echo

|  |  |  |
| --- | --- | --- |
| VISIT | Study visit | 0: baseline  1: visit 1  2: visit 2  4: visit 4 |
| R300\_age | Age at the time | days |
| SBP | Systolic blood pressure | mmHg |
| DBP | Diastolic blood pressure | mmHg |
| MBP | Mean blood pressure | mmHg |
| SINUSR | Sinus or ectopic atrial rhythm | 1: yes  2: no |
| HEARTBLK | Complete heart block | 1: yes  2: no |
| PACEDRHY | Pace rhythm | 1: yes  2: no |
| ATRIALF | Atrial flutter | 1: yes  2: no |

R301: Echo 2D (every field is needed)

|  |  |  |
| --- | --- | --- |
| VISIT | Study visit | 0: baseline  1: visit 1  2: visit 2  4: visit 4 |
| Echo\_age | Age at echo | days |
| ACCEPTABLE | Remove if not acceptable | 1: yes  2: no |
| CLV\_PRES | Left ventricle present | 1: yes  2: no |
| CLV\_EDLAD2 | LV End-diastolic endo. long axis dimension | cm |
| CLV\_EDV\_MS | LV End-diastolic volume | ml |
| CLV\_ESV\_MS | LV End-systolic volume | ml |
| CLV\_VM\_MS | LV ventricular mass | Gm |
| CRV\_EDLAD2 | RV End-diastolic long axis dimension | cm |
| CRV\_EDSAD2 | RV End-diastolic short axis dimension | cm |
| CRV\_EDA | RV End-diastolic area |  |
| CRV\_ESA | RV End-diastolic area |  |
| CRV\_SDD\_LAX | Subcostal dimension end diastolic LAX | cm |
| CRV\_SDS\_LAX | Subcostal dimension end systolic LAX | cm |

  R302: Echocardiography 3D (every field is needed)

|  |  |  |
| --- | --- | --- |
| GENOTYPE | Apo E genotype |  |

R340: Angiography Core Lab

|  |  |  |
| --- | --- | --- |
| BSA | Body surface area |  |
| PROXLPA | Mid-main LPA diameter | mm |
| DISTLPA | Proximal Left Lower Lobe diameter | Mm |
| LPA\_DIA\_RAT | Left Lower to Mid-main LPA ratio |  |
| LP A\_ABNORM | LPA abnormality | 1: yes  2: no |
| LPA\_STENO | Severity of LPA stenosis | % |
| PROXRP A | Mid-main RPA diameter | Mm |
| rpa\_z | Proximal Right Lower Lobe Z-score |  |
| RPA\_DIA\_RAT | Right Lower to Mid-main RPA ratio |  |
| RPA\_ABNORM | RPA Abnormality | 1: yes  2: no |
| RPA\_STENO | Severity of LPA stenosis | % |
| CONFLU | Pulmonary artery confluence | 1: yes  2: no |
| COND\_STENOS | Conduit/Shunt stenosis | 1: yes  2: no |

Key\_info

|  |  |  |
| --- | --- | --- |
| sescore | US CENSUS SES SCORE |  |
| poverty | BELOW FED POVERTY LEVEL | % |
| transplant | Heart transplant | 1: yes  2: no |
| diedinOR | Died in OR? | 1: yes  2: no |
| death | Died? | 1: yes  2: no |
| eventyn | Death/transplant by the end of SVR trial | 1: yes  2: no |
| dtx1yr | Death or Transplant by 1 yr post randomization | 1: yes  2: no |
| nwdsae | Number of SAEs prior to Norwood discharge |  |
| Pnd\_sae | Number of SAEs post Norwood discharge to month12 |  |
| numsae | total number of SAEs from Norwood operation to month 12 |  |
| nwdcomp | Number of complications after Norwood operation during Norwood hospitalization |  |
| Pnd\_comp | Number of complications post Norwood discharge to month 12 |  |