Outcomes dataset has 78 variables for 304 patients on BMT protocol #0402 GVHD Prophylaxis and each patient has one record. This is the most important dataset in this data submission.

Notes in the last column of below table are provided by BMT CTN DCC to facilitate better understanding of the submitted datasets:

- **CRF** indicates this variable is from EMMES Case Report Form, as reported by the transplant center. The name of the CRF is shown in the column for easy reference.
- **EMMES** indicates this variable is from EMMES Enrollment System, as study implemented per protocol.
- **RECODE** indicates this variable is from computation for analysis purpose based on other data source. Algorithm and computation method are provided for reference.
- **ERC** indicates this variable is from the BMT #0402 Endpoint Review Committee adjudication. ERC adjudicated the data in a blinded manner based on the site-reported data in CRFs as well as some clinical notes from the sites. ERC –adjudicated outcomes should supersede the site-reported data if there would be any discrepancy.
- **CIBMTR** indicates this variable is data retrieval from the CIBTMR data system. CIBMTR data were reviewed by the CIBMTR physicians prior to the data transfer to Emmes DCC.
<table>
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<tr>
<th>#</th>
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<td>EMMES – this indicated BMT CTN Protocol #</td>
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<td>DATETIME22.3</td>
<td>Transplant Date</td>
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<td>Date to Neutrophil Engraftment</td>
<td>CRF - HEM</td>
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<td>Date of VOD</td>
<td>RECODE - This is the date of toxicity evaluation on CRF-TX7 to confirm VOD (TX7EVLDT, TX7VODET='1').</td>
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<td>Date of Grade 3-5 HUS/TTP</td>
<td>RECODE - This is the date of toxicity evaluation on CRF-TX7 to report grades 3-5 HUS/TTP/TMA (TX7EVLDT, TX7DIC).</td>
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<td>Maximum Toxicity Grade</td>
<td>RECODE - this is the maximum grade of Grades 3-5 toxicity that patient experienced, computed based on CRF-TX7 data. If null, it indicates that patient’s maximum toxicity grade was 0-2.</td>
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<td>RECODE - this is the toxicity evaluation date for the computed maximum toxicity grade, based on variable TX7EVLDT on CRF-TX7</td>
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<td>Maximum Mucositis Score by Day 21</td>
<td>RECODE - This calculation is based on CRF-MUC data that collected twice weekly for the first three weeks post-transplant. The mucositis score is the sum of average ulceration score and average erythema score. This variable is the maximum of all computed mucositis scores by Day 21 post-transplant.</td>
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# Variables in Creation Order

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<tr>
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<th>Variable</th>
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<td>4.2</td>
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<td>Average Mucositis Score by Day 21</td>
<td>RECODE – There can be up to six computed mucositis scores for each patient based on CRF-MUC data. This is the average of derived mucostis scores.</td>
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<td>Date of Randomization</td>
<td>EMMES - this is the start date of the patient on this study.</td>
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<td>Center Name</td>
<td>EMMES – this is the name of the transplant center where the recipient was enrolled from</td>
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<td>RECODE - this is based on race and secondary race reported on DEM form and combine into several big race categories.</td>
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<td>RECODE - this is based on death date from all available data sources including CRF-DTH, CIBMTR follow-up data</td>
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<td>RECODE - this is based on the last follow-up date from all available data sources including CRF, CIBMTR follow-up data and ERC adjudication</td>
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<td>RECODE - this is the computed age of years at enrollment based on DOB on CRF-DEM form</td>
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<td>Primary Cause Of Death</td>
<td>ERC - this is based on primary cause of death reported on CRF-DTH form and adjudicated by ERC</td>
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<tr>
<td>#</td>
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<td>Format</td>
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<td>Label</td>
<td>Data Source / Notes</td>
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<td>Acute GVHD Max Grade</td>
<td>ERC – This is the ERC adjudicated maximum overall grade of acute GVHD, including all acute GVHD (before day 100, after day 100). ERC adjudicated the maximum grade based on the weekly acute GVHD assessment and some clinical notes as needed.</td>
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<tr>
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<td>AGVHD Grade II-IV Date</td>
<td>ERC – This is the ERC adjudicated onset date of grades 2-4 acute GVHD. If acute GVHD grade less than 2, this is blank.</td>
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<td>AGVHD Grade III-IV Date</td>
<td>ERC - This is the ERC adjudicated onset date of grades 3-4 acute GVHD. If acute GVHD grade less than 3, this is blank.</td>
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<td>Patient eligibility adjudicated by ERC</td>
<td>ERC - this is the ERC adjudication if patient is eligible for study</td>
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<td>Platelet Recover 20K Date</td>
<td>CIBMTR - This is the date to platelet recovery to 20k.</td>
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<td>Variable</td>
<td>Type</td>
<td>Len</td>
<td>Format</td>
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<td>Data Source / Notes</td>
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<td>Platelet Recover 50K Date</td>
<td>CIBMTR - This is the date to platelet recovery to 50k.</td>
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<td>Donor-recipient CMV status</td>
<td>RECODE - this is computed based on donor’s CMV status from CRF-TXP (CMVSTAT) and recipient’s CMV status from CIBMTR (DCMVPR)</td>
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<td>RECODE - this is computed based on donor’s gender from CRF-DEM and recipient’s gender from CIBMTR (DONORGENDER)</td>
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<td>ERC - This is the ERC adjudicated maximum grade of chronic GVHD. 0 indicates no chronic GVHD.</td>
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<td>Variable</td>
<td>Type</td>
<td>Len</td>
<td>Format</td>
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<td>DATETIME22.3</td>
<td>Chronic GVHD Onset Date</td>
<td>ERC - This is the ERC adjudicated onset date of chronic GVHD.</td>
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<td>Chronic GVHD Max Date</td>
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<td>ERC - This is the ERC adjudication if patient had disease progression or relapse.</td>
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<td>Progression Relapse Date</td>
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<td>ERC - This is the hospital discharge date for initial transplant verified by ERC.</td>
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<td>Days of Neutrophil Recovery from Transplant</td>
<td>RECODE, this is the days from date of transplant to date of neutrophil recovery (=ANCDTI - TXDTTXP)</td>
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<td>#</td>
<td>Variable</td>
<td>Type</td>
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<td>Format</td>
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<td>Neutrophil Recovery Outcome</td>
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<td>Neutrophil Recovery Indicator for competing risk (1=event, 2=death, 0=end study)</td>
<td>RECODE - this is the indicator for cumulative incidence of neutrophil recovery (0=End Study, 1=Engraft, 2=Death) Death is considered a competing risk in the cumulative incidence analysis for neutrophil recovery.</td>
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<td>Days of Relapse from Transplant</td>
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<td>Months of Relapse from Transplant</td>
<td>RECODE - this is the months from transplant date to date of relapse (=relapseday/30.4)</td>
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<td>Relapse Outcome</td>
<td>RECODE - this is the outcome for relapse post transplant</td>
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<td>Relapse Indicator for competing risk (1=event, 2=death, 0=end study)</td>
<td>RECODE - this is the indicator for cumulative incidence of relapse (0=End Study, 1=Relapse, 2=Death) Death is considered a competing risk in the cumulative incidence analysis for relapse.</td>
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<td>Days of Grade 2-4 Acute GVHD from Transplant</td>
<td>RECODE - this is days from transplant to date of Grade 2-4 acute GVHD (=agvh24dt-TXDTTXP).</td>
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<td></td>
<td>Grade 2-4 Acute GVHD Outcome</td>
<td>RECODE - this is the outcome of Grades 2-4 acute GVHD Post Transplant endpoint</td>
</tr>
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<td>Grade 2-4 Acute GVHD Indicator for competing risk (1=event, 2=death, 0=end study)</td>
<td>RECODE - this is the cumulative incidence indicator for Grades 2-4 acute GVHD post transplant endpoint. (0=End Study, 1=GVH234, 2=Death) Death is considered a competing risk in the cumulative incidence analysis for acute GVHD.</td>
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<td>#</td>
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<td>Format</td>
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<td>56</td>
<td>gvh34day</td>
<td>Num</td>
<td>8</td>
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<td>Days of Grade 3-4 Acute GVHD from Transplant</td>
<td>RECODE - this is days from transplant to date of Grade 3-4 acute GVHD (=agvh34dt-TXDTTXP).</td>
</tr>
<tr>
<td>57</td>
<td>gvh34outcome</td>
<td>Char</td>
<td>9</td>
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<td>Grade 3-4 Acute GVHD Outcome</td>
<td>RECODE - this is the outcome of Grades 3-4 acute GVHD post transplant endpoint</td>
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<tr>
<td>58</td>
<td>gvh34_CI</td>
<td>Num</td>
<td>8</td>
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<td></td>
<td>Grade 3-4 Acute GVHD Indicator for competing risk (1=event, 2=death, 0=end study)</td>
<td>RECODE - this is the cumulative incidence indicator for Grades 3-4 acute GVHD post transplant endpoint. (0=End Study, 1=GVH34, 2=Death) Death is considered a competing risk in the cumulative incidence analysis for acute GVHD.</td>
</tr>
<tr>
<td>59</td>
<td>cgvhdday</td>
<td>Num</td>
<td>8</td>
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<td>Days of Chronic GVHD from Transplant</td>
<td>RECODE - this is the days from date of transplant to date of maximum chronic GVHD (=cgvhdt-TXDTTXP).</td>
</tr>
<tr>
<td>60</td>
<td>cgvhmon</td>
<td>Num</td>
<td>8</td>
<td></td>
<td></td>
<td>Months of Chronic GVHD from Transplant</td>
<td>RECODE - this is the months from date of transplant to date of maximum chronic GVHD (=cgvhdday/30.4).</td>
</tr>
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<td>Len</td>
<td>Format</td>
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<td>Data Source / Notes</td>
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<td>61</td>
<td>cgvhdoutcome</td>
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<td>Chronic GVHD Outcome</td>
<td>RECODE - this is the outcome of chronic GVHD post transplant endpoint</td>
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<tr>
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<td>cgvhd_CI</td>
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<td>Chronic GVHD Indicator for competing risk (1=event, 2=death, 0=end study)</td>
<td>RECODE - this is the cumulative incidence indicator for chronic GVHD post transplant endpoint. (0=End Study, 1=cGVHD, 2=Death) Death is considered a competing risk in the cumulative incidence analysis for chronic GVHD.</td>
</tr>
<tr>
<td>63</td>
<td>vodday</td>
<td>Num</td>
<td>8</td>
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<td></td>
<td>Days of VOD from Transplant</td>
<td>RECODE - this is the days from date of transplant to the date of toxicity evaluation that confirmed VOD. (=VODDATE–TXDTTXP).</td>
</tr>
<tr>
<td>64</td>
<td>VODoutcome</td>
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<td>VOD Outcome</td>
<td>RECODE - this is the outcome of confirming VOD based on toxicity evaluation</td>
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<td>65</td>
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<td>VOD Indicator for competing risk (1=event, 2=death, 0=end study)</td>
<td>RECODE - this is the cumulative incidence indicator for VOD confirmation. (0=End Study, 1=VOD, 2=Death) Death is considered a competing risk in the cumulative incidence analysis for VOD.</td>
</tr>
<tr>
<td>66</td>
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<td>Days of Grade 3-5 HUS/TTP from Transplant</td>
<td>RECODE - this is the days from date of transplant to the date of toxicity evaluation that reported grades 3-5 HUS/TTP/TMA. (=HUSDATE –TXDTTXP).</td>
</tr>
<tr>
<td>67</td>
<td>HUSoutcome</td>
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<td>Grade 3-5 HUS/TTP Outcome</td>
<td>RECODE - this is the outcome of reporting grades 3-5 HUS/TTP/TMA.</td>
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<tr>
<td>68</td>
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<td></td>
<td>Grade 3-5 HUS/TTP Indicator for competing risk (1=event, 2=death, 0=end study)</td>
<td>RECODE - this is the cumulative incidence indicator for reporting grades 3-5 HUS/TTP/TMA. (0=End Study, 1=HUS, 2=Death) Death is considered a competing risk in the cumulative incidence analysis for HUS.</td>
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<td>Format</td>
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<tr>
<td>69</td>
<td>disday</td>
<td>Num</td>
<td>8</td>
<td></td>
<td></td>
<td>Days of 1st Hospital Discharge from Transplant</td>
<td></td>
</tr>
<tr>
<td>70</td>
<td>DISoutcome</td>
<td>Char</td>
<td>9</td>
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<td></td>
<td>1st Hospital Discharge Outcome</td>
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<td>71</td>
<td>DIS_CI</td>
<td>Num</td>
<td>8</td>
<td></td>
<td></td>
<td>1st Hospital Discharge Indicator for competing risk (1=event, 2=death, 0=end study)</td>
<td></td>
</tr>
<tr>
<td>72</td>
<td>osday</td>
<td>Num</td>
<td>8</td>
<td></td>
<td></td>
<td>Overall Survival Days post Transplant</td>
<td></td>
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<tr>
<td>73</td>
<td>ossrcens</td>
<td>Num</td>
<td>8</td>
<td></td>
<td></td>
<td>Overall Survival post Transplant Censor Indicator (1=event)</td>
<td></td>
</tr>
<tr>
<td>#</td>
<td>Variable</td>
<td>Type</td>
<td>Len</td>
<td>Format</td>
<td>Informat</td>
<td>Label</td>
<td>Data Source / Notes</td>
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<tr>
<td>74</td>
<td>rosv234day</td>
<td>Num</td>
<td>8</td>
<td></td>
<td></td>
<td>Grade 2-4 Acute GVHD-free Survival Days post Randomization</td>
<td>RECODE - this is the days from date of transplant to the death or last follow up or date of grade 2-4 acute GVHD</td>
</tr>
<tr>
<td>75</td>
<td>rgv234outcome</td>
<td>Char</td>
<td>9</td>
<td></td>
<td></td>
<td>Grade 2-4 Acute GVHD-free Survival post Randomization Outcome</td>
<td>RECODE - this is the outcome for grade 2-4 acute GVHD free survival post randomization endpoint</td>
</tr>
<tr>
<td>76</td>
<td>rosv234</td>
<td>Num</td>
<td>8</td>
<td></td>
<td></td>
<td>Grade 2-4 Acute GVHD-free Survival post Randomization Censor Indicator (1=event)</td>
<td>RECODE - this is the censor indicator for grade 2-4 acute GVHD free survival post randomization endpoint</td>
</tr>
<tr>
<td>77</td>
<td>rfsday</td>
<td>Num</td>
<td>8</td>
<td></td>
<td></td>
<td>Relapse-Free Survival Days post Transplant</td>
<td>RECODE - this is the days from transplant date to the death or last follow up or date of relapse</td>
</tr>
<tr>
<td>78</td>
<td>rfsrvcens</td>
<td>Num</td>
<td>8</td>
<td></td>
<td></td>
<td>Relapse-Free Survival post Transplant Censor Indicator (1=event)</td>
<td>RECODE - this is the censor indicator for relapse-free survival endpoint. (0=End Study, 1=Relapse/Death)</td>
</tr>
</tbody>
</table>
Algorithm used for the Recode and ERC Adjudications

Algorithm for Acute GVHD Grade:

- The acute GVHD algorithm calculates the grade based on the organ (skin, GI and liver) stage and etiology/biopsy reported on the weekly GVHD form.
- If none of the etiologies for skin, upper GI, lower GI, or liver are reported as GVHD, then the overall grade is 0.
- If multiple etiologies are specified for lower GI or liver, the organ system will be down-staged by 1.
- If an upper GI biopsy is negative, upper GI symptoms are down-staged.
- If GVHD is not listed as an etiology for upper GI then upper GI symptoms are down-staged.
- Each organ contributes to the overall grade; while to get an overall grade, it does not necessarily need all organ symptoms. Different organ/stage determine different grade. Details below:

<table>
<thead>
<tr>
<th>Grade 0:</th>
<th>Grade III:</th>
</tr>
</thead>
<tbody>
<tr>
<td>No skin rash and No protracted nausea and vomiting and No diarrhea or diarrhea &lt; 500 and Bilirubin &lt; 2.0</td>
<td>Skin-No rash to Rash &gt; 50% with Diarrhea &gt; 1000 or severe abdominal pain or Bilirubin 3.1 - 15</td>
</tr>
<tr>
<td>Grade I:</td>
<td>Grade IV:</td>
</tr>
<tr>
<td>Skin rash 25-50 % and No diarrhea or diarrhea &lt; 500 and Bilirubin &lt; 2.0</td>
<td>Skin-Generalized Erythroderma with Bullus Formation and Desquamation or Bilirubin &gt; 15</td>
</tr>
<tr>
<td>Grade II:</td>
<td></td>
</tr>
<tr>
<td>Skin rash &gt;50% or Diarrhea &gt;500 or Bilirubin 2.0 - 3.0 or Persistent nausea/vomiting</td>
<td></td>
</tr>
</tbody>
</table>

Algorithm for Chronic GVHD: Limited vs Extensive (Definition from CIBMTR forms)

- Limited – localized skin involvement and/or hepatic dysfunction due to chronic GVHD
- Extensive – one or more of the following:
1. generalized skin involvement; or,
2. liver histology showing chronic aggressive hepatitis, bridging necrosis or cirrhosis; or,
3. involvement of eye: Schirmer’s test with < 5 mm wetting; or
4. involvement of minor salivary glands or oral mucosa demonstrated on labial biopsy; or
5. involvement of any other target organ

Note on the sample size:
The BMT CTN 0402 study enrolled 314 participants in total. There were 10 participants who received Bu/Cy conditioning regimen on the study and results were published as an early cohort prior to the completion of the study. These 10 participants were excluded from the primary manuscript per protocol team decision. Three participants did not receive study transplant. This OUTCOMES dataset includes 304 patients as above mentioned. Some other datasets (e.g enrollment dataset ENRA) are keeping data for all the enrolled patients for completeness.