

CHANGE LOG: RELEASE NOTES

REDCap ABMTRR Cell Therapy Project

Version 2.22.6 (Released May 2021)

Changes in this version:

FORM: Patient Information 2.22.6

REMOVAL OF QUESTION(S)

Removal of all upload file fields

FORM: Disease Classification 2.22.6

REMOVAL OF QUESTION(S)

- Removal of all upload file fields
- LYMPHOMA – removed the known / unknown field for Deauville score

CHANGE TO QUESTION(S)

- ALL classification - Update of choices from the dropdown list

FORM: ALL Preinfusion 2.22.6

CHANGE TO QUESTION(S)

- Section 3. DISEASE TREATMENT PRIOR TO PREPARATIVE REGIMEN / INFUSION. Addition of *Bridging to Cell Infusion* for Therapy type

FORM: Lymphoma Pre Infusion 2.22.6

REMOVAL OF QUESTION(S)

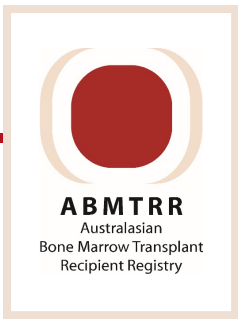
- Section 7. DISEASE TREATMENT PRIOR TO INFUSION. Removal of *Known / Unknown* questions for each therapy line (1-7) for therapy: *Systemic therapy / Intrathecal therapy / Intraocular therapy / Radiation therapy / Surgery*.
- Removal of all upload file fields

CHANGE TO QUESTION(S)

- Section 7. DISEASE TREATMENT PRIOR TO INFUSION. *Specify regimen*: Update of choices from the dropdown list
- Section 7. DISEASE TREATMENT PRIOR TO INFUSION. *Other systemic drugs*: Update of choices from list

ADDITIONAL QUESTION(S)

- Section 7. DISEASE TREATMENT PRIOR TO INFUSION. Addition of question for each treatment:



Variable: lympre_tx1_bridge Branching logic: [lympre_tx1_yn] = '1'

Line of therapy was bridging to cell infusion? Yes No reset

FORM: CELL THERAPY Preinfusion 2.22.6

ADDITIONAL QUESTION(S)

- Section 1. PATIENT IDENTIFICATION. Addition of *Date of first referral*.
- Section 5. PRODUCT IDENTIFICATION. Addition of *Final product read for shipping / Final product shipped*.
- Section 5. PRODUCT IDENTIFICATION. Additional question: *Actual setting of infusion INPATIENT / OUTPATIENT*.
- Section 9. LYMPHODEPLETING THERAPY. Removal of therapy table, each therapy is now listed and shows sub-questions when YES is selected for each therapy. Additional questions include: *Was there a XXXX dose reduction YES | NO, if yes, % XXXX dose reduction / Reason XXXX dose reduction*.

9. LYMPHODEPLETING THERAPY	
Lymphodepleting therapy given	<input checked="" type="radio"/> Yes <input type="radio"/> No reset <small>given prior to infusion</small>
Bendamustine	<input checked="" type="radio"/> Yes <input type="radio"/> No reset
Bendamustine total dose	<input type="text"/> <small>Daily dose x number of days</small>
Bendamustine units	<input type="text"/>
Was there a bendamustine dose reduction	<input checked="" type="radio"/> Yes <input type="radio"/> No reset
% bendamustine dose reduction	<input type="text"/>
Reason bendamustine dose reduction	<input type="text"/>
Bendamustine Date started	<input type="text"/> Today D-M-Y

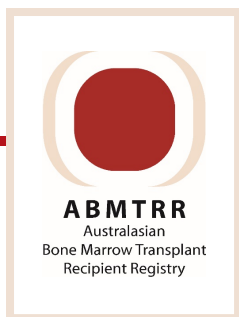
- Section 9. LYMPHODEPLETING THERAPY. Addition of Cytarabine to therapy list.
- Section 10. PATIENT ASSESSMENT. Addition of question: *ECOG prior to cell therapy*. ECOG Performance Status 0 – 4 (including reference table).
- Section 11. COMORBID CONDITIONS. Addition of question: *Were there any co-existing diseases or organ impairment present according to the HCT comorbidity index (HCT-CI)? YES | NO* - (within 3 months prior to the infusion, unless noted as ANY history in the list of coexisting diseases). If yes, complete the Comorbidities.

FORM: CELL THERAPY Infusion 2.22.6

CHANGE TO QUESTION(S)

- Section 3 – CELL DOSES. Text for reporting total number of cells now reads: *Report total number of cells in the product given (not cell per kg)*

ADDITIONAL QUESTION(S)



- Section 2 – INFUSION. New calculated fields for follow up dates (based on date of infusion). Questions will only appear when *Product was infused* = YES.

Follow up Dates (based on date of infusion)		
30 day follow up date	<input type="text" value="30-10-2020"/> View equation	
100 day follow up date	<input type="text" value="08-01-2021"/> View equation	
6 month follow up date	<input type="text" value="30-03-2021"/> View equation	
1 year follow up date	<input type="text" value="30-09-2021"/> View equation	

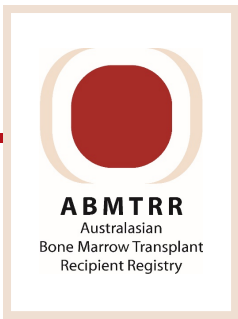
FORM: CELL THERAPY Follow Up 2.22.6

REMOVAL OF QUESTION(S)

- Section 5 – PERIPHERAL BLOOD COUNT RECOVERY. Removal of question – Initial recovery previously reported?
- Section 7 – Current Haematology Values. Removal of unknown fields for each Haematology type.
- Section 15 - MAXIMUM LAB VALUES SINCE LAST REPORT. Removal of Interferon gamma and interferon date questions

CHANGE TO QUESTION(S)

- Section 4. BEST RESPONSE TO CELLULAR THERAPY. Questions are hidden if Tisagenlecleucel or Axicabtagene ciloleucel are selected for *Name of Product*.
- Section 7 – Current Haematology Values. Data value unit change for Neutrophils from % to $\times 10^9/L$. Current data values have been updated to reflect the change.
- Section 11. TOXICITIES – CYTOKINE RELEASE SYNDROME. CRS therapy – removal of *No Therapy Given* option from the therapy list and corrected spelling for Tocilizumab.
- Section 12 – TOXICITIES - NEUROTOXICITY. *Treatment for neurotoxicity* – add *Anakinra* to list of treatments.
- Section 12 – TOXICITIES - NEUROTOXICITY. *Treatment for neurotoxicity* – removal of *No Therapy Given* option from the therapy list.
- Section 14. GRADE 3 OR 4 TOXICITIES (CTCAE v5.0). *Developed grade 3 organ toxicity* – removal of text '*Answer for Kymriah product only*'.
- Section 14. GRADE 3 OR 4 TOXICITIES (CTCAE v5.0). *Developed Grade 4 organ toxicity* – removal of text '*Applies to all products*'.
- Section 14. GRADE 3 OR 4 TOXICITIES (CTCAE v5.0). For Grade 3 and Grade 4 organ toxicity – removal of '*specify organ*', and replaced question: *Specify toxicity* – with dropdown choices, dependent on organ involvement.



14. GRADE 3 OR 4 TOXICITIES (CTCAE v5.0)
 Complete for 30 day, 100 day and 6 month follow up only

Developed grade 3 organ toxicity Yes No Unknown reset

Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self care Activities of Daily Living

Organ involved reset

Specify toxicity

- Capillary leak syndrome
- Cardiac arrhythmia
- Hypertension
- Hypotension
- Left ventricular systolic dysfunction
- Myocardial infarction
- New or worsening heart failure
- Pericardial effusion
- Pericarditis
- Restrictive cardiomyopathy
- Thromboembolic event

- Section 12 – TOXICITIES - NEUROTOXICITY. *Treatment for neurotoxicity* – removal of *No Therapy Given* option from the therapy list.
- Section 16. INFECTION. Replacement of organism text field with a dropdown list.

ADDITIONAL QUESTION(S)

- Section 5 – PERIPHERAL BLOOD COUNT RECOVERY. Addition of questions: (ANC recovery)

5. PERIPHERAL BLOOD COUNT RECOVERY
 Complete this section for 30 day, 100 day, 6 month, 1 and 2 year follow up

Initial neutrophil recovery reset
ANC >= 0.5x10⁹/L

Subsequent ANC decline following initial recovery Yes No reset
ANC < 0.5 for >=3days since last report

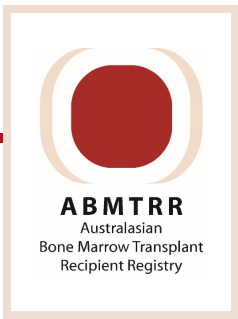
ANC decline date D-M-Y

Did ANC recover Yes No reset
ANC recovered and maintained >=0.5x10⁹/L

ANC recovery date D-M-Y

Initial platelet recovery reset
Plt >= 20x10⁹/L, earliest recovery date is at least 7 days after last platelet transfusion

- Section 7 – Current Haematology Values. Addition of a new question: *Growth factors were given <= 7 days prior* YES | NO
- Section 11. TOXICITIES – CYTOKINE RELEASE SYNDROME. *CRS Therapy given* YES | NO.
- Section 11. TOXICITIES – CYTOKINE RELEASE SYNDROME. If Tocilizumab is selected as CRS Therapy given, Doses of tocilizumab is required 1 | 2 or more.
- Section 11. TOXICITIES – CYTOKINE RELEASE SYNDROME. CRS Symptoms. If Vasopressor(s) given = Yes, additional questions apply:



Hypotension requiring therapy	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown <small>reset</small>
Date of onset	<input type="text"/> <small>Today</small> D-M-Y
Intravenous fluids given	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown <small>reset</small>
Vasopressor(s) given	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown <small>reset</small>
Number of vasopressors used for therapy	<input type="text"/>
Vasopressor(s) used	<input type="checkbox"/> Phenylephrine <input type="checkbox"/> Norepinephrine <input type="checkbox"/> Epinephrine <input type="checkbox"/> Dopamine <input type="checkbox"/> Vasopressin <input checked="" type="checkbox"/> Other
other vasopressor	<input type="text"/>

- Section 11. TOXICITIES – CYTOKINE RELEASE SYNDROME. CRS Symptoms. If *Any features related to MAS/HLH = Yes*, additional questions apply:

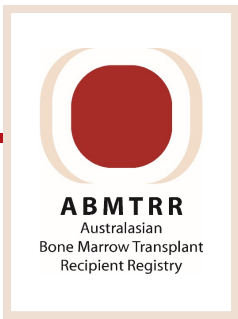
Any features related to MAS/HLH	<input checked="" type="radio"/> Yes <input type="radio"/> No <small>reset</small> <small>Macrophage activation syndrome / haemophagocytic lymphohistiocytosis</small>
MAS/HLH date onset	<input type="text"/> <small>Today</small> D-M-Y
Splenomegaly associated with MAS/HLH	<input type="radio"/> Yes <input type="radio"/> No <small>reset</small>
MAS/HLH confirmed by BM Biopsy	<input type="radio"/> Yes <input type="radio"/> No <small>reset</small>
Lowest fibrinogen level	<input type="text"/> <small>at time of MAS/HLH diagnosis</small>
fibrinogen units	<input type="radio"/> mg/dL <input type="radio"/> mg/L <small>reset</small>
Fibrinogen date of sample	<input type="text"/> <small>Today</small> D-M-Y
Highest Triglyceride level	<input type="text"/> <small>at time of MAS/HLH diagnosis</small>
triglyceride units	<input type="radio"/> mg/dL <input type="radio"/> mmol/L <small>reset</small>
Triglyceride date of sample	<input type="text"/> <small>Today</small> D-M-Y

- Section 12 – TOXICITIES - NEUROTOXICITY. *Treatment for neurotoxicity was given YES|NO*
- Section 16. INFECTION. Addition of *other organism* field if other organism is selected from the dropdown list.

FORM: Lymphoma Post Infusion 2.22.6

ADDITIONAL QUESTION(S)

- Section 5. DISEASE STATUS AT TIME OF EVALUATION (for this reporting period). Current disease status by PET (metabolic) criteria = *Not Assessed* new question: *Reason not assessed (at 12 months)*.

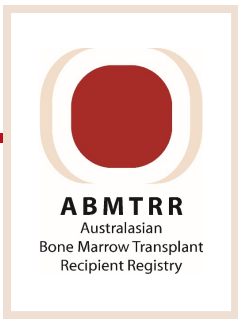


5. DISEASE STATUS AT TIME OF EVALUATION (for this reporting period)

Current disease status by CT (radiographic) criteria	<input type="text" value="Complete remission (CR)"/>
Date assessed	<input type="text" value="Today"/> D-M-Y
Current disease status by PET (metabolic) criteria	<input type="text" value="Not assessed"/>
Reason not assessed	<input type="text" value="at 12 months"/>

FORM: New Malignancy 2.22.6

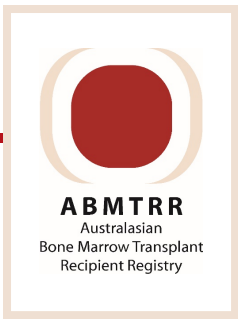
REMOVAL OF QUESTION(S)
Removal of all upload file fields



NEW FORM: Preinfusion Documentation 2.22.6

The new form will now contain all the attached documentation related to pre infusion.

Event Name: Cell Therapy		
AID (ABMTRR ID)	100001	
Date of infusion	<input type="text"/> <small>Documentation relates to this infusion date</small>	
Assessments prior to infusion		
FISH at diagnosis	<input type="text"/> <small>Documentation relates to this infusion date</small>	Upload file
Karyotyping at diagnosis	<input type="text"/> <small>Documentation relates to this infusion date</small>	Upload file
Pathology report at diagnosis	<input type="text"/> <small>Documentation relates to this infusion date</small>	Upload file
FISH between diagnosis and last assessment	<input type="text"/> <small>Relevant for AML and ALL</small>	Upload file
Karyotyping between diagnosis and last assessment	<input type="text"/> <small>Relevant for AML and ALL</small>	Upload file
FISH at last assessment	<input type="text"/> <small>Documentation relates to this infusion date</small>	Upload file
Karyotyping at last assessment	<input type="text"/> <small>Documentation relates to this infusion date</small>	Upload file
MRD at last assessment	<input type="text"/> <small>Lymphoma</small>	Upload file
Lymphoma transformation prior to infusion		
Pathology report at lymphoma transformation	<input type="text"/> <small>Documentation relates to this infusion date</small>	Upload file
Karyotyping at lymphoma transformation	<input type="text"/> <small>Documentation relates to this infusion date</small>	Upload file
FISH at lymphoma transformation	<input type="text"/> <small>Documentation relates to this infusion date</small>	Upload file
Monoclonal gammopathy of renal significance documentation		
MRGS pathology report	<input type="text"/> <small>Documentation relates to this infusion date</small>	Upload file
HLA reports		
HLA recipient	<input type="text"/> <small>Documentation relates to this infusion date</small>	Upload file
HLA donor	<input type="text"/> <small>Documentation relates to this infusion date</small>	Upload file
HLA second donor	<input type="text"/> <small>Documentation relates to this infusion date</small>	Upload file
HLA third donor	<input type="text"/> <small>Documentation relates to this infusion date</small>	Upload file



NEW FORM: Postinfusion Documentation 2.22.6

The new form will now contain all the attached documentation related to post infusion.

Event Name: Cell Therapy Follow Up		
AID (ABMTRR ID)	100001	
Infusion date	<input type="text" value=""/>	<input type="button" value="v"/>
<small>* must provide value</small>	<small>Documentation relates to this infusion date</small>	
Follow up period	<input type="radio"/> 30 day <input type="radio"/> 100 day <input type="radio"/> 6 month <input type="radio"/> 1 year <input type="radio"/> 2 year <input type="radio"/> >2year	
<small>* must provide value</small>	<small>reset</small>	
Best disease response post infusion		
FISH at best response	<input type="button" value="H"/>	Upload file
Karyotyping at best response	<input type="button" value="H"/>	Upload file
Pathology report at best response	<input type="button" value="H"/>	Upload file
	<small>Lymphoma</small>	
Disease relapse or progression		
FISH at relapse/progression	<input type="button" value="H"/>	Upload file
Karyotyping at relapse/progression	<input type="button" value="H"/>	Upload file
Pathology at relapse/progression	<input type="button" value="H"/>	Upload file
	<small>e.g. lymphoma biopsy report</small>	
Assessments at current follow up		
FISH at this follow up	<input type="button" value="H"/>	Upload file
Karyotyping at this follow up	<input type="button" value="H"/>	Upload file
New malignancy		
New malignancy diagnosis	<input type="button" value="H"/>	Upload file
New malignancy donor/cell product derived	<input type="button" value="H"/>	Upload file
PTLD biopsy report	<input type="button" value="H"/>	Upload file
Cause of death		
Autopsy report	<input type="button" value="H"/>	Upload file
Other		
other documentation	<input type="button" value="H"/>	Upload file