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Form 18: Donor Derived Cell-free DNA Collec

19851 Question Year Group

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Not Started

1

Date of collection

Question Added: 18 NOV 2023
CollectionDate

2

Indication for test

- ☐ Routine surveillance
- ☐ Follow-up of treated rejection
- ☐ Follow-up of elevated dd-cfDNA result
- ☐ Clinical indication/for cause

Question Added: 18 NOV 2023
Indication

2a

Rejection date

Missing Reason:
☐ Unknown

RejectionDateCode

2b

Elevated dd-cfDNA result
date

Missing Reason:
☐ Unknown

ElevatedResultDateCode

2c

Clinical indication/for
cause

- ☐ Clinical symptoms/exam findings
CIClinicalSymptomsExamFindings
- ☐ Echo concern
CIEchoConcern
- ☐ Suspected medication nonadherence (e.g. by
history, fluctuating levels, etc.)
CISMNA
- ☐ New or increased donor specific antibody
CINOIDSA
- ☐ Isohemagglutinin against ABOi graft
CIIAAG
- ☐ Change in biomarker
CICChangeInBiomarker
- ☐ Change in immunosuppression
CICChangeInImmunosuppression

2c.i

New or
increased donor
specific
antibody detail

- ☐ HLA antibody
DonorAntibodyHlaAntibody
- ☐ Non-HLA antibody
DonorAntibodyNonHlaAntibody

2c.ii

Change in
biomarker
detail

- ☐ BNP/NT-pro-BNP
- ☐ hs-troponin
- ☐ Other, specify

BiomarkerChangeSpecify

BiomarkerChange

Was this patient changed to CNI-free

ImmunosuppressionChange

2c.iii maintenance immune		<input type="radio"/> Yes	
3	Donor-derived cell-free DNA result (%)	<input type="text"/>	<div>Range Information Too Low: < 0 Normal: Between 0 and 100 Question Zone: > 101 Red Flag Zone: > 101</div> <div>Missing Reason: <input type="radio"/> Failed Test <input type="radio"/> Not Applicable</div> <div>Question Added: 18 NOV 2023</div> <div>DNAResultPercentCode</div>
3a	Donor-derived cell-free DNA result (Absolute value)	<input type="text"/>	<div>Missing Reason: <input type="radio"/> Failed Test <input type="radio"/> Not Applicable</div> <div>Question Added: 18 NOV 2023</div> <div>DNAResultAbsCode</div>
3b	Indicate Test Manufacturer	<div><input type="radio"/> Allosure (CareDx) <input type="radio"/> Prospera (Natera) <input type="radio"/> MyTAI <input type="radio"/> Other, specify</div> <div><input type="text"/></div> <div>ManufacturerSpecify</div>	<div>Question Added: 18 NOV 2023</div> <div>Manufacturer</div>
4	Was a biopsy obtained within 14 - 30 days of the dd-cfDNA assessment	<div><input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown</div>	<div>Question Added: 18 NOV 2023</div> <div>BiopsyObtained</div>
5a	Biopsy date	<input type="text"/>	<div>Missing Reason: <input type="radio"/> Unknown</div> <div>BiopsyDate</div>
5b	ACR grade (like rejection form 2b)	<div><input type="radio"/> 0R <input type="radio"/> 1R <input type="radio"/> 2R <input type="radio"/> 3R <input type="radio"/> Unknown</div>	<div>ACRGrade</div>
5c	AMR grading (like rejection form 2c, 2c.i, 2c.ii)	<div><input type="radio"/> Both histology and immunofluorescence/immunohistochemistry performed (ie. C4d or C3d) <input type="radio"/> Did not access biopsy for evidence of AMR <input type="radio"/> Only assessed histology/ did not perform immunofluorescence/immunohistochemistry (ie. C4d or C3d) <input type="radio"/> Unknown</div>	<div>AMRGrade</div>
5c.i	pAMR Grading 2013 revised ISHLT grading system for pAMR: J Heart Lung Transplant 2013 Dec 32(12):1147-62.) pAMR: pathologic antibody mediated rejection (0, 1h, 1i, 2, 3)	<div><input type="radio"/> 0 (negative) <input type="radio"/> 1h <input type="radio"/> 1i <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> Positive for AMR but pAMR score not known</div>	<div>PAMRSCOR</div>
5c.ii	AMR Findings If only accessed histology/ did not perform immunofluorescence or immunohistochemistry (ie. C4d or C3d)	<div><input type="radio"/> No histologic features AMR <input type="radio"/> Positive histologic features AMR (ie. Vasculitis/pericapillaritis)</div>	<div>BIOPAMR</div>

5d Was EMB gene expression profiling done (i.e., MMDx) ☐ Yes
☐ No
☐ Unknown

GeneExpProfile

5d.i Was MMDx normal/abnormal? ☐ Normal
☐ Abnormal

MMDxNormAb

5d.i.1 TCMR? ☐ TCMR present
☐ TCMR absent
☐ TCMR-like changes not meeting threshold for TCMR

TCMR

5d.i.2 ABMR? ☐ ABMR present
☐ ABMR absent
☐ ABMR-like changes/not meeting threshold for ABMR

ABMR

5d.i.3 Injury ☐ None
☐ Mild
☐ Some
☐ Moderate
☐ Severe

Injury

5d.i.4 Parenchymal dedifferentiation ☐ None
☐ Mild
☐ Some
☐ Moderate
☐ Severe

ParenDediff

Action and Response to Cell Free DNA Results

5 Immune suppression ☐ No change made
☐ Decreased dose or target trough levels
☐ Increased dose or increased target trough levels
☐ Treatment for rejection (complete rejection form)
☐ Other, specify

ImmuneSuppressionSpecify

Question Added: 18 NOV 2023
ImmuneSuppression

6 Biopsy ☐ No biopsy ordered
☐ Biopsy ordered as planned per protocol
☐ Biopsy ordered outside of protocol
☐ Other, specify

BiopsySpecify

Biopsy

Question Added: 18 NOV 2023

6a **Next surveillance (only if no biopsy obtained)**

- ☐ No change to protocol based surveillance
- ☐ Earlier than planned surveillance (example labs, clinic visit, echo)
- ☐ Other, specify

NextSurveillanceSpecify

NextSurveillance

7 **Were there any additional management strategies in reponse to cell free DNA result?**

Missing Reason:

- ☐ No other strategies

Question Added: 18 NOV 2023
AddlMgmtStrategyCode

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