tournicare

CASE REPORT FORM

PROTOCOL: Tcarev1.2

TOURNICARE SAFETY, ACCURACCY AND EASE OF USE ASSESSMENT

Participant Study Number: | | | | | |

ADVERSE EVENTS

Participant Number						

General Instructions for Completion of the Case Report Forms (CRF)

Completion of CRFs

- A CRF must be completed for each study participant who is successfully enrolled (received at least one dose of study drug)
- For reasons of confidentiality, the name and initials of the study participant should **not** appear on the CRF.

General

- Please print all entries in BLOCK CAPITAL LETTERS using a **black** ballpoint pen.
- All text and explanatory comments should be brief.
- Answer every question explicitly; do not use ditto marks.
- Do not leave any question unanswered. If the answer to a question is unknown, write "**NK**" (Not Known). If a requested test has not been done, write "**ND**" (Not Done). If a question is not applicable, write "**NA**" (Not Applicable).
- Where a choice is requested, **cross (X)** the appropriate response.

Correction of Errors

- **Do not** overwrite erroneous entries, or use correction fluid or erasers.
- Draw a straight line through the entire erroneous entry without obliterating it.
- Clearly enter the correct value next to the original (erroneous) entry.
- Date and initial the correction.

PARTICIPANT INFORMATION		
Participant Number		
Inclusion/exclusion criteria *Patient must meet all criteria to eligible for the study	Met all ☐1.	Not met* ☐2.
Date of Informed Consent	D D M M M Y Y Y Y	
Gender	☐1 Male ☐2 Female	
Age		
Arm circumference		
Arm Width		

	Systolic	**Diastolic**	**Heart Rate**
Self measurement control monitor			
Self measurement Tournicare			

	Tournicare		**Control BP monitor**		
Side	Systolic	Diastolic	Systolic	Diastolic	side
Right					Left
Left					Right

ADVERSE EVENTS – *make multiple copies of this page if required*

Adverse event name	
Intensity	☐1 Mild ☐2 Moderate ☐3 Severe
If SAE specify:	☐1 Death ☐2 Life-threatening ☐3 Persistent or symptomatic disability or incapacity ☐4 Hospitalisation or prolongation of hospitalisation ☐5 Congenital anomaly or birth defect ☐6 Other important medical event
Onset Date	D D M M M Y Y Y Y
End Date	D D M M M Y Y Y Y **OR** ☐ Ongoing at the end of study
Therapy	☐1 None ☐2 Drug ☐3 Other ☐4 Drug and other
Outcome	☐1 Recovered ☐2 Recovering ☐3 Recovering with sequelae ☐4 Continuing ☐5 Fatal ☐99 Not Known
Relationship to Study drug	☐1 Certain ☐2 Probable ☐3 Possible ☐4 Unlikely ☐5 Not related ☐6 Unclassified

FINAL STUDY OUTCOME

Participant Number						

FINAL STUDY OUTCOME

Subject has completed the study? ☐1

Completion date : D D M M M Y Y Y Y

Reason not completed:

Remarks: _____

_____

_____

Investigator's Statement: I have reviewed the data recorded in this CRF and confirm that the data are complete and accurate

Investigator (Full name): _____

Investigator Signed? ☐1

Signature Date: D D M M M Y Y Y Y