



FIBRINOGEN EARLY IN
FEISTY II
SEVERE TRAUMA STUDY

**HEALTH ECONOMIC ANALYSIS PLAN
FOR A RANDOMISED CONTROLLED
TRIAL COMPARING FIBRINOGEN
CONCENTRATE WITH
CRYOPRECIPITATE IN TRAUMATIC
HAEMORRHAGE**

Version 1.0

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Abbreviations

AN-SNAP	Australian National Subacute and Non-Acute Patient Classification
ANZIC-RC	Australian and New Zealand Intensive Care Research Centre
AUC	Area under the curve
AUD	Australian dollars
CPI	Consumer price index
CRF	Case report form
Cryo	Cryoprecipitate
DAOH ₉₀	Days alive out of hospital at home at 90 days
FC	Fibrinogen concentrate
FEISTY	Fibrinogen Early In Severe Trauma study
FFP	Fresh frozen plasma
FibC	Clauss fibrinogen
FIBTEM	Fibrin-based thromboelastometric test
HRQoL	Health-related quality of life
ICER	Incremental cost-effectiveness ratio
ICU	Intensive care unit
IHACPA	Independent Health and Aged Care Pricing Authority
MHP	Major Haemorrhage Protocol
NHCDC	National Hospital Cost Data Collection
NMB	Net monetary benefit
NZD	New Zealand dollar
PCC	Prothrombin complex concentrate
PPP	Purchasing power parity
QALY	Quality-adjusted life year
RBCs	Red blood cells
RCT	Randomised controlled trial
ROTEM	Rotational thromboelastometry
TEG FF	Thromboelastography functional fibrinogen
USD	United States dollar

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1. Administrative information

This Health Economics Analysis Plan outlines the planned analysis of economic data for a multi-centre randomised controlled trial comparing fibrinogen concentrate (FC) with cryoprecipitate (Cryo) in traumatic haemorrhage. It should be read in conjunction with the published trial protocol, which provides detailed information on the objective, design, outcomes, data management, and statistical considerations.

2. Background

Major haemorrhage, a life-threatening bleeding event often requiring massive transfusion, is associated with high mortality and low health-related quality of life (HRQOL) following trauma.¹⁻³ Approximately one in four trauma patients with major haemorrhage die in hospital, with two-thirds of these deaths occurring within the first 24 hours after admission, while about one-third die within one year of injury.¹ Although overall mortality among trauma patients requiring transfusion has decreased in recent years, mortality associated with massive transfusion has remained unchanged and high, at approximately 48%.² Despite gradual improvements in HRQOL over time, the majority of survivors fail to regain their pre-injury or population-level HRQOL even 12 months after trauma.³ Consequently, major haemorrhage in trauma patients continues to represent a significant public health concern requiring urgent attention.

Trauma patients with major haemorrhage consume substantial healthcare resources and generate considerable costs. Approximately 84% of patients with major haemorrhage trauma are admitted to an intensive care unit (ICU), with a median hospital stay of at least 20 days, including 6-8 days in the ICU.^{1,2} In the United Kingdom, the estimated inpatient cost of treating

a major haemorrhage case in 2013 was £18,100, of which 42% was attributable to ICU care, 26% to general ward care, 17% to theatre costs, and 13% to blood products.⁴ The annual national cost of trauma-related haemorrhage was estimated at £85 million. However, evidence on the costs of trauma-related haemorrhage in Australia and New Zealand is lacking. Given the substantial resource utilisation associated with major haemorrhage, identifying cost-effective management strategies is essential to inform policy decisions, optimise healthcare resource allocation, and reduce overall healthcare costs.

The transfusion of blood and blood products, such as red blood cells (RBCs), platelets, fresh frozen plasma (FFP), prothrombin complex concentrate (PCC), and cryoprecipitate (Cryo), is a cornerstone of the resuscitation of patients with major haemorrhage. Since fibrinogen is the first clotting factor depleted in exsanguinating haemorrhage, leading to hypofibrinogenaemia, current clinical guidelines recommend fibrinogen supplementation using either Cryo or FC to rapidly restore haemostasis.^{5,6} Cryo is a commonly used source of fibrinogen and contains several clotting factors that facilitate haemostasis. However, Cryo must be stored at temperatures below -18°C and, once thawed, must be transfused within 6 hours as it cannot be refrozen.

FC offers several potential advantages over Cryo, including rapid reconstitution, precise dosing, viral inactivation during processing, and a lower risk of transfusion-related adverse events.^{7,8} In the United States, the acquisition cost of FC is approximately USD \$1,000 per gram, while the acquisition cost of 5-6 units of Cryo, equivalent to approximately 1 gram of FC, is around USD \$300-400, though additional processing and wastage costs apply to Cryo.⁷ Economic modelling suggests that, even after accounting for estimated 28% wastage rate for Cryo, the acquisition cost of FC would need to decrease by roughly 44% or result in savings of 0.25-0.66 ICU days to achieve cost-parity with Cryo in the United States.⁹

There is limited evidence on the comparative safety, efficacy, and cost-effectiveness of the two products. The Fibrinogen Replenishment in Surgery (FIBERS) trial, conducted in Canada, included 735 cardiac surgery patients with significant bleeding and hypofibrinogenaemia following cardiopulmonary bypass.¹⁰ The authors found FC to be non-inferior to Cryo in terms of the number of blood components transfused within 24 hours post-bypass and concluded that FC was cost-effective when considering blood product and hospital resource utilisation costs within 28 days of surgery.^{10,11} However, whether these findings are generalisable to patients with trauma-related major haemorrhage remains uncertain, highlighting the need for further evaluation of the clinical effectiveness and cost-effectiveness of FC versus Cryo in trauma-setting.

The FEISTY pilot trial demonstrated that FC can be administered to trauma patients significantly faster than Cryo, highlighting its logistical advantage in time-critical bleeding scenarios.¹² However, high-quality evidence directly comparing the two products remains limited. The ongoing FEISTY II trial in Australia and New Zealand is evaluating the clinical effectiveness of FC vs. Cryo in traumatic major haemorrhage. An accompanying economic evaluation is essential to determine the cost-effectiveness of FC relative to the current standard of care.

3. Trial design

The FEISTY II Trial is a prospective, phase III, multi-centre, randomised, controlled, two arm parallel, and open label trial of trauma patients with major haemorrhage. The trial is underway and aims to enrol 900 severely injured trauma patients. Eligible participants must meet all the following criteria:

- Age \geq 18 years, and
- Judged to have active haemorrhage by treating clinician, and
- Activation of the local massive haemorrhage protocol (MHP) and/or transfusion of emergency blood products, and
- FIBTEM A5 \leq 10 mm, or TEG FF A10 \leq 15 mm, or Clauss fibrinogen (FibC) \leq 2 g/L.

Patients are excluded from the study if any of the following criteria apply:

- Injury judged to be incompatible with survival
- Randomisation cannot occur within 6 hours of hospital presentation
- Known pregnancy
- Known genetic or drug-induced coagulation disorder
- Known objection to receiving blood products
- Prior dedicated fibrinogen replacement during the current presentation
- Severe pre-existing physical or mental disability, or severe comorbidity, likely to interfere with outcome assessment
- Participation in a competing study

Approximately 450 patients per arm will be treated with either FC or Cryo, according to their ROTEM/TEG/FibC results and initial randomisation arm, during the first 24 hours after enrolment. Each patient will receive a 3 g dose of fibrinogen, administered as either FC or Cryo. The fibrinogen dose for this trial was determined based on pilot data, published evidence from other clinical trials, and consultation with the Australian Red Cross Lifeblood and the New Zealand Blood Service. Due to variability in fibrinogen concentration between Cryo products, patients randomised to the Cryo arm in Australia will receive either 10 units of whole blood Cryo, 4 units of apheresis Cryo, or 10 units of split apheresis Cryo, while patients in New

Zealand will receive 3 units of apheresis Cryo. For safety reasons, crossover between treatment arms will only be permitted after administration of two treatment doses.

The primary outcome of the trial is days alive out of hospital at home at 90 days after randomisation (DAOH₉₀). Secondary outcomes that are relevant to this economic analysis include all-cause mortality and health-related quality of life measures at 90 days, 6 months, and 12 months after randomisation, assessed using the EQ-5D-5L instrument.⁷ ClinicalTrials.gov: NCT05449834.

4. Objective

The objective of this study is to assess the cost-effectiveness of FC compared to Cryo for the management of major haemorrhage and hypofibrinogenemia in severely injured trauma patients.

5. Economic evaluation

A full economic evaluation will be conducted alongside the FEISTY trial, comparing FC with Cryo for the management of major haemorrhage and hypofibrinogenemia in severely injured trauma patients. This trial-based cost-effectiveness analysis will adhere to intention-to-treat principles and will adopt a healthcare provider perspective, specifically that of the government funder. Cost-effectiveness results will include the cost per QALY gained and cost per a life-year saved from randomisation to 90 days. Additionally, the cost-effectiveness of FC vs. Cryo over a 12-month follow-up will be explored from a healthcare provider perspective. This extended analysis will incorporate the costs of hospital readmissions and inpatient

rehabilitation between 90 days and 12 months, in addition to healthcare utilisation costs incurred between randomisation and 90 days. Findings will be reported in accordance with the 2022 Consolidated Health Economic Evaluation Reporting Standards.¹³ As the follow-up period does not exceed 12 months, discounting of costs and benefits will not be applied.

5.1 Data variables

Data collected during the trial through case report forms (CRFs) and used for this economic evaluation will include:

1. Socio-demographic characteristics: age; sex; and ethnicity.
2. Baseline clinical characteristics: injury type; illness severity (Injury Severity Score); Glasgow Coma Scale score; and organ failure status.
3. Baseline blood characteristics: full blood count; blood group; platelet count; international normalized ratio; FC; rotational thromboelastometry (ROTEM); thromboelastography (TEG); and Clauss fibrinogen assay results.
4. Blood product use within 24 hours of randomisation: FC; Cryo; red blood cells (RBCs); fresh frozen plasma (FFP); platelets; and prothrombin complex concentrate (PCC).
5. Hospitalisation details: the date and time of index hospital and ICU admission and discharge; discharge destination following the index hospital stay (home, long-term care facility, other acute hospital, or rehabilitation centre); dates of admission and discharge for any subsequent readmissions to a hospital, long-term care facility, transitional living centre, or rehabilitation centre up to 90 days post-discharge; hospital readmission status (yes/no) between 90 days and 180 days and between 180 days and 12 months; and the patient's location at the time of follow-up assessments at 180 days and 12 months.

6. Clinical outcomes: cause, date, and time of death; and health-related quality of life at 90 days, 180 days, and 12 months post-randomisation.

5.2 Health outcomes

The health outcomes will include life years and QALYs derived from survival and HRQoL data collected at 90 days, 180 days, and 12 months post-randomisation. QALYs will be estimated using HRQoL data collected via the EQ-5D-5L instrument.¹⁴ EQ-5D-5L responses will be converted into utility values using a scoring algorithm based on Australian national value sets, where 0 represents death and 1 represents full health.¹⁵ QALYs will be calculated using the area under the curve (AUC) method using, assuming linear interpolation between randomisation and each follow-up time point (90 days, 180 days, and 12 months). A utility value of zero will be assigned at baseline (randomisation). The difference in life years and QALYs between the FC and Cryo groups will be reported as incremental effectiveness.

5.3 Health resource use

Healthcare resource use, including hospitalisations, rehabilitation, and blood products, will be quantified for each trial arm using patient-level data collected through CRFs. Blood product utilisation within 24 hours of randomisation will be recorded as grams for FC and as bags for Cryo, platelets, RBCs, FFP, and PCC. Hospitalisations, with admission and discharge dates reported by patients, will include the index hospitalisation (ICU and ward stays) and all hospital readmissions, including rehabilitation, from randomisation to Day 90. In addition, healthcare resource use will encompass any inpatient rehabilitation services, or other care, such as transitional living centres or long-term care facilities, up to 90 days post-randomisation.

Resource use reported at follow-up assessments at 180 days and 12 months will also be captured for survivors, or up to the time of death for non-survivors. Any hospital readmission reported by a patient at 180 days and 12 months post-randomisation, for which admission and discharge dates are unavailable, will be counted as one hospitalisation. If a patient reports no discharge from a facility (acute hospital, rehab centre, or long-term care facility) at 90 days and identifies the same location as their current location at 180 days, a corresponding continuous stay will be assumed at the 180-day assessment (e.g., length of stay = 90 days). Similarly, if a patient reports being in an acute hospital, rehabilitation centre, or long-term care facility at 180 days and reports the same location as their current location at 12 months, a continuous stay will be assumed at the 180-day assessment (e.g., length of stay = 6 months).

5.4 Cost estimation

Costs will be estimated by assigning unit costs to the corresponding quantities of healthcare resource use (Table 1). Because ICU and ward stay costs represent the largest contributors to overall expenditure,⁴ and their most recent available unit costs are from 2024, all costs will be reported in 2024 Australian dollars (AUD), using the 2024 annual average exchange rate of rate of 1 New Zealand dollar (NZD) = 0.92 AUD, unless more recent unit costs become available. Costs may also be presented in international currencies (e.g., Euro or United States dollar) using purchasing power parity (PPP) conversion factors from the World Bank.¹⁶ Cost estimates will be stratified by country to account for national variations in practice patterns and unit prices.

As blood products are issued in unit bags, costs will be assigned to account for wastage (for example, if three and a half units of RBCs are transfused, the cost of four units will be

assigned). For transfused Cryo and FFP, the estimated cost of transfusion laboratory staff time associated with component preparation and issuing will also be added. The cost of Cryo will include the time required to thaw, relabel, and issue 10–15 units, which has been reported to take approximately 15 minutes.⁹ Accordingly, the associated labour cost is estimated at AUD \$7.9 for Australia and \$8.9 for New Zealand, based on medical laboratory technician (blood bank) hourly rates.^{17,18} In Australia, a weekly salary of AUD \$1,250 for a medical laboratory technician (Grade 2, 2nd year of experience), as specified by the Fair Work Commission, corresponds to an hourly rate of AUD \$32.9 (assuming a 38-hour work week). This hourly rate is then adjusted to 2024 values using the Wage Price Index (0.96) from the Australian Bureau of Statistics¹⁹. Similarly, in New Zealand, an annual salary of NZD \$79,039 for a medical laboratory technician (Step 5) under the Laboratory Workers' Collective Agreement (1 November 2025 – 31 January 2027) corresponds to an hourly rate of NZD \$39.9 (assuming a 38-hour work week).

For Australia, base costs for blood products will be sourced from the National Blood Authority Annual Report 2023-24 (Table 1).²⁰ For New Zealand, corresponding costs will be obtained from the New Zealand Blood Service Price Schedule 2022-2023.²¹ The costed blood products will include FC, Cryo, RBCs, FFP, platelets, and PCC, with unit costs standardised by volume and currency. The exception will be FC, for which a unit cost of AUD \$1,000 per gram will be applied, reflecting the price charged by CSL during the trial. Published FC unit costs of AUD \$889 per FC gram in Australia and AUD \$856 per gram in New Zealand will be included in sensitivity analyses (Section 5.6).^{20,21} For Australia, if fewer than 5 units of Cryo are transfused in a single episode, the unit cost of apheresis Cryo will be applied; if 5 or more units of Cryo are transfused, the whole-blood apheresis Cryo cost will be used. For New Zealand, the cost of Cryo (apheresis leucodepleted) will be applied.

The unit cost of whole-blood RBCs will be set at AUD \$375 per bag for Australia and AUD \$328 for New Zealand. For FFP in Australia, the average cost of whole-blood and apheresis FFP will be applied (AUD \$188), whereas in New Zealand the cost of apheresis FFP (AUD \$248 per bag) will be used. The cost of platelets will be based on the average cost of whole-blood-derived platelets (AUD \$257 per bag) and apheresis platelets (AUD \$550 per bag) in Australia. For New Zealand, the unit cost of apheresis leucodepleted platelets (AUD \$958 per bag) will be used. The cost of PCC will be set at AUD \$327 per 500 IU in Australia and AUD\$464 per 500 IU in New Zealand.

Unit cost of AUD \$6,000 per ICU bed-day in Australia will be estimated by multiplying the national ICU rate of AUD \$250 per hour by 24 hours. This estimate is consistent with the 2023-24 National Pricing Model by the Independent Health and Aged Care Pricing Authority (IHACPA).²² For New Zealand, the daily ICU cost of NZD \$5,500 reported in 2017 will be inflated to 2024 using the relevant health CPI, yielding an estimated cost of NZD \$6,930 per bed-day, which is equivalent to AUD \$6,375 per bed-day.²³

For medical ward stays during the index hospitalisation and subsequent hospital readmissions, a cost of AUD \$2,673 per bed-day will be applied for Australia. This estimate is derived from the National Hospital Cost Data Collection (NHCDC) of the IHACPA by dividing the 2023-24 national average cost of AUD \$6,415 per admitted acute separation by the average length of stay of 2.4 days.²⁴ Similarly, for New Zealand, a cost of AUD \$2,351 per bed-day will be applied, based on the 2019 reported cost of NZD \$5,068 per hospitalisation with an average length of stay of 2.4 days, inflated to 2024.

For inpatient rehabilitation, a unit cost of AUD \$1,850 per bed-day or \$49,039 per case will be applied for both Australia and New Zealand, which is derived from the 2023-24 average cost of major multiple trauma (AN-SNAP v5 codes 5AP1-5AP2) in the NHCDC of the IHACPA.²⁴

Similarly, stays in transitional living centres will be costed at AUD \$1,609 per bed-day or AUD \$27,517 per case for both countries. These estimates are derived from the unit costs of shorter-term care for adults aged 18-64 (AN-SNAP v5 code 5ES3).

Table 1. Unit costs applied to healthcare resource use in the FEISTY trial (1 NZD = 0.92 AUD)

Country	Cost item	Unit cost (local currency)	Cost year	Inflation rate from the cost year to 2024	Unit cost applied to resources	Source
Australia and New Zealand	Fibrinogen concentrate	AUD \$1,000 per 1 g	2024	1.00	AUD \$1,000 per 1 g	Charged cost by CSL during the trial
Australia	Salary of medical laboratory technician (Grade 2, 2nd year of experience)	AUD \$32.9 per hour or AUD \$1,250 per week	2025	0.96	AUD \$31.6 per hour or AUD \$1,200 per week	Fair Work Commission. Health Professionals, Medical Scientists and Support Services (Victoria) State Reference Public Sector Modern Award 2018. Medical laboratory technician, Grade 2, 2nd year of experience. https://www.abs.gov.au/statistics/economy/price-indexes-and-inflation/wage-price-index-australia/latest-release .
	Cryoprecipitate (whole blood leucodepleted)	AUD 167 (30-40 ml)	2024	1.00	AUD 167 (30-40 ml)	National Blood Authority. Annual Report 2023-24. https://www.blood.gov.au/annual-report
	Cryoprecipitate (apheresis)	AUD \$340 per bag (54-66 ml)	2024	1.00	AUD \$340 per bag (54-66 ml)	
	Red blood cells (whole blood leucodepleted)	AUD \$375 per bag (200 ml)	2024	1.00	AUD \$375 per bag (200 ml)	
	Fresh frozen plasma (whole blood)	AUD \$156 per bag (295 ml)	2024	1.00	AUD \$156 per bag (295 ml)	
	Fresh frozen plasma (apheresis)	AUD \$220 per bag (295 ml)	2024	1.00	AUD \$220 per bag (295 ml)	
	Platelets (whole blood)	AUD \$257 per bag (160 ml)	2024	1.00	AUD \$257 per bag (160 ml)	
	Platelets (apheresis)	AUD \$550 per bag (100-400 ml)	2024	1.00	AUD \$550 per bag (100-400 ml)	

	Prothrombin complex (plasma derived)	AUD \$327 per 500 IU	2024	1.00	AUD \$327 per 500 IU	
	ICU stay	AUD \$6,000 per bed-day	2024	1.00	AUD \$6,000 per bed-day	Independent Health and Aged Care Pricing Authority (2025). National Pricing Model 2024–25 https://www.ihacpa.gov.au/sites/default/files/2024-03/national_pricing_model_technical_specifications_2024-25.pdf
	Medical ward	AUD \$2,673 per bed-day	2024	1.00	AUD \$2,673 per bed-day	Independent Health and Aged Care Pricing Authority (2025). National Hospital Cost Data Collection Public Sector Report, 2023-24 https://www.ihacpa.gov.au/resources/national-hospital-cost-data-collection-public-sector-2023-24
	Readmission	AUD \$2,673 per bed-day or AUD \$6,415 per case	2024	1.00	AUD \$2,673 per bed-day or AUD \$6,415 per case	
	Inpatient rehabilitation (AN-SNAP v5 code 5AP1 5AP2)	AUD \$1,850 per bed-day or AUD \$49,039 per case	2024	1.00	AUD \$1,850 per bed-day or AUD \$49,039 per case	
	Transitional living centre (AN-SNAP v5 code 5ES3)	AUD \$1,609 per bed-day or AUD \$27,517 per case	2024	1.00	AUD \$1,609 per bed-day or AUD \$27,517 per case	
New Zealand	Salary of medical laboratory technician	NZD \$39.9 per hour or NZD \$79,039	2024	1.00	AUD \$36.7 per hour or AUD \$72,716	Health New Zealand. Laboratory Workers' Collective Agreement 1 November 2025 – 31 January 2027. Medical Laboratory Technicians, Step 5. https://static.info.content.health.nz/docs/health-pros/employment-agreements/apex-medical-laboratory-workers-ca-1nov2025-31jan2027-signed.pdf
	Cryoprecipitate (apheresis leucodepleted)	NZD \$487 per bag	2023	1.04	AUD \$465 per bag	New Zealand Blood Service. Blood Product Price Schedule 2022-2023.

Red blood cells (concentrated leucodepleted)	NZD \$343 per bag	2023	1.04	AUD \$328 per bag	https://redbook.streamliners.co.nz/NZBS%20Price%20List%20for%202022-23.pdf
Fresh frozen plasma (apheresis leucodepleted)	NZD \$260 per bag	2023	1.04	AUD \$248 per bag	
Platelets (apheresis leucodepleted)	NZD \$1,001 per bag	2023	1.04	AUD \$958 per bag	
Prothrombinex VF	NZD \$485 per 500 IU	2023	1.04	AUD \$464 per 500 IU	
ICU stay	NZD \$5,500 per bed-day	2017	1.26	AUD \$6,375 per bed-day	PHARMAC Cost Resource Manual, Version 3. https://pharmac.govt.nz/medicine-funding-and-supply/the-funding-process/policies-manuals-and-processes/economic-analysis/cost-resource-manual/ Price index for inputs of the medical and other health care services industry in New Zealand https://figure.nz/chart/YvhuEptsu1jLB2QF-UznEajs1ezvmtMWM
Medical ward	NZD \$2,112 per bed-day	2019	1.21	AUD \$2,351 per bed-day	Cost Resource Manual. The 2018/19 cost-weight unit price is NZD \$5,068. https://www.pharmac.govt.nz/medicine-funding-and-supply/the-funding-process/policies-manuals-and-processes/economic-analysis/cost-resource-manual/ Price index for inputs of the medical and other health care services industry in New Zealand https://figure.nz/chart/YvhuEptsu1jLB2QF-UznEajs1ezvmtMWM
Readmission	NZD \$2,112 per bed-day or NZD \$5,068 per case	2019	1.21	AUD \$2,351 per bed-day or AUD \$5,641 per case	
Inpatient rehabilitation (AN-SNAP v5 code 5AP1 5AP2)	AUD \$1,850 per bed-day or AUD \$49,039 per case	2024	1.00	AUD \$1,850 per bed-day or AUD \$49,039 per case	Independent Health and Aged Care Pricing Authority (2025). National Hospital Cost Data Collection Public Sector Report, 2023-24 https://www.ihacpa.gov.au/resources/national-hospital-cost-data-collection-public-sector-2023-24
Transitional living centre (AN-SNAP v5 code 5ES3)	AUD \$1,609 per bed-day or AUD \$27,517 per case	2024	1.00	AUD \$1,609 per bed-day or	

					AUD \$27,517 per case	
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5.5 Cost-effectiveness analyses

This economic evaluation will be conducted using Stata Statistical Software (StataCorp, 2023: Release 18. College Station, TX). Missing data will be addressed in accordance with the practical guidance.²⁵ The process will begin with a descriptive analysis to assess the extent and distribution of missing data by trial group, identify potential patterns of missingness, and examine associations with baseline characteristics and observed outcomes. These analyses will inform assumptions about the underlying missing data mechanism and guide the choice of appropriate methods for handling missingness. Specifically, multiple imputation and likelihood-based models will be applied, and their results compared to identify the most suitable approach.

Between-group differences in mean per-patient costs and QALYs will be estimated using a generalized linear model with either a gamma distribution and log link function or a Gaussian distribution and identity link, depending on the distribution of the data. This approach is appropriate because healthcare cost data are often right-skewed and heteroscedastic, making the gamma distribution with a log link well suited for modelling positive, non-normally distributed outcomes, while the Gaussian distribution is suitable for approximately normally distributed outcomes. Consistent with the primary clinical analyses, models will be adjusted for prespecified baseline covariates and stratification variables used in the main trial to improve precision and account for any chance imbalances between treatment groups.

The cost-effectiveness of FC vs. Cryo will be evaluated using multiple approaches. Mean per-patient costs and health outcomes for each treatment group will be compared, and both the incremental cost-effectiveness ratio (ICER) and net monetary benefit (NMB) will be calculated.¹⁴ Incremental costs and incremental effectiveness will be estimated using maximum likelihood estimation, with results reported alongside 95% uncertainty intervals. The ICER will

be calculated by dividing the difference in mean per-patient costs between the FC vs. Cryo groups by the difference in health outcomes.

NMB will be calculated by valuing QALY gains at an assumed willingness-to-pay (WTP) threshold of AUD \$50,000 per QALY and subtracting incremental costs and will be reported along with 95% confidence intervals. A positive NMB will indicate that FC is cost-effective at this threshold, whereas a negative NMB will suggest it is not.

5.6 Sensitivity and scenario analyses

Several sensitivity analyses will be performed to assess the robustness of the cost-effectiveness findings. In particular, probabilistic sensitivity analyses using non-parametric bootstrapping with 1,000 replications will be conducted to quantify uncertainty around incremental costs and effects arising from sampling variation in the trial data. The bootstrapped ICERs will be plotted on cost-effectiveness planes and a cost-effectiveness acceptability curve (CEAC) will be generated to show the probability that the FC is cost-effective at different willingness-to-pay (WTP) thresholds. The probability of FC being cost-effective compared to Cryo will be presented across a range of WTP thresholds, from AUD \$10,000 to AUD \$200,000 per QALY gained.

Additionally, deterministic (one-way) sensitivity analyses will be undertaken to test the robustness of base-case results to changes in key assumptions. Parameters to be varied will include unit costs of blood products and ICU/ward stays ($\pm 20\%$), adjustments of base cost to 2025 values through inflation or deflation, and substitution of hospital readmission patterns using data from Campbell et al. in the United Kingdom.⁴ Scenario analyses will further explore

alternative time horizons of 3 months and 12 months. Results will be presented as tornado diagrams and ICER ranges.

5.7 Subgroup analyses

Consistent with the FEISTY trial, pre-specified subgroup analyses for this trial-based economic evaluation will include:

- Traumatic brain injury (TBI): patients with vs. without TBI
- Jurisdiction: Australia vs. New Zealand
- Baseline fibrinogen: ≤ 1 g/L vs. >1 g/L
- Pre-hospital time: ≥ 120 minutes vs. <120 minutes

Subgroup effects will be assessed via interaction terms (treatment \times subgroup) in cost, QALY, and net monetary benefit models. Results will be interpreted cautiously given limited power for interaction testing, p-values will be considered exploratory and accompanied by 95% CIs. Where appropriate, ICERs and NMB will be presented by subgroups, with cost-effectiveness planes used to illustrate uncertainty.

6. Presentation of results (dummy tables and figures)

The following tables and figures will be presented to summarise the findings from the cost-effectiveness analysis.

Table 1. Baseline characteristics of study participants by treatment groups

Table 2. Resource utilisation and costs by treatment groups

Table 3. Summary of cost-effectiveness results

Figure 1. Cost-effectiveness plane (cost per a quality-adjusted life year gained)

Figure 2. Cost-effectiveness plane (cost per life-year saved)

Figure 3. Cost effectiveness acceptability curves

Supplementary Table 1. Unit costs (AUD)

Supplementary Table 2. Comparison of baseline characteristics between study participants with and without missing data

Supplementary Table 3. Subgroup analyses

7. Ethics approval

Where possible, informed consent will be obtained from participants. In time-critical trauma cases, consent will be sought from the next of kin or, if unavailable, enrolment may proceed under the emergency care research process with senior clinician approval. Subsequent consent will be obtained as soon as possible. Ethics approval: GCHHS HREC/2022/QGC/85034.

8. References

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9. Appendix: Case Report Form

FEISTY II CRF	Patient Study ID <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/>
 <p data-bbox="596 640 1166 992">FIBRINOGEN EARLY IN FEISTY II SEVERE TRAUMA STUDY</p> <h1 data-bbox="424 1077 1110 1162">Case Report Form</h1> <p data-bbox="520 1249 1018 1368">Fibrinogen Early In Severe Trauma StudY</p> <p data-bbox="557 1451 979 1507">www.feisty.org.au</p>	

<h1 style="margin: 0;">FEISTY II CRF</h1> <h2 style="margin: 0;">Screening Assessment</h2>		Patient Study ID 																								
Patient details																										
1.1	Date of birth	<table style="border-collapse: collapse; margin-left: auto; margin-right: auto;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> </tr> <tr> <td style="text-align: center; font-size: 8px;">d</td> <td style="text-align: center; font-size: 8px;">d</td> <td style="text-align: center; font-size: 8px;">m</td> <td style="text-align: center; font-size: 8px;">m</td> <td style="text-align: center; font-size: 8px;">y</td> <td style="text-align: center; font-size: 8px;">y</td> </tr> </table>							d	d	m	m	y	y												
d	d	m	m	y	y																					
1.2	Sex at birth	<input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Indeterminate																								
1.3	Date and time of hospital admission	<table style="border-collapse: collapse; margin-left: auto; margin-right: auto;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> </tr> <tr> <td style="text-align: center; font-size: 8px;">d</td> <td style="text-align: center; font-size: 8px;">d</td> <td style="text-align: center; font-size: 8px;">m</td> <td style="text-align: center; font-size: 8px;">m</td> <td style="text-align: center; font-size: 8px;">y</td> <td style="text-align: center; font-size: 8px;">y</td> <td style="text-align: center; font-size: 8px;">y</td> <td style="text-align: center; font-size: 8px;">y</td> <td style="text-align: center; font-size: 8px;">h</td> <td style="text-align: center; font-size: 8px;">h</td> <td style="text-align: center; font-size: 8px;">m</td> <td style="text-align: center; font-size: 8px;">m</td> </tr> </table>													d	d	m	m	y	y	y	y	h	h	m	m
d	d	m	m	y	y	y	y	h	h	m	m															
Inclusion Criteria (Must answer YES to all to be eligible)																										
2.1	Adult affected by Trauma (≥ 18 yrs)	<input type="checkbox"/> Yes <input type="checkbox"/> No																								
2.2	Judged to have significant haemorrhage	<input type="checkbox"/> Yes <input type="checkbox"/> No																								
2.3	Activation of local massive haemorrhage protocol (MHP) and or transfusion of Emergency blood product	<input type="checkbox"/> Yes <input type="checkbox"/> No																								
2.4	FIBTEM ≤ 10mm or TEG FF A10 ≤ 15mm or FibC ≤ 2g/L	<input type="checkbox"/> Yes <input type="checkbox"/> No																								
Please enter the result you used to meet inclusion (one only)																										
FIBTEM mm TEG FF mm FibC g/l																										
Exclusion Criteria (Must answer NO to all to be eligible)																										
3.1	Known Pregnancy	<input type="checkbox"/> Yes <input type="checkbox"/> No																								
3.2	Injury judged incompatible with survival	<input type="checkbox"/> Yes <input type="checkbox"/> No																								
3.3	Known objection to blood products	<input type="checkbox"/> Yes <input type="checkbox"/> No																								
3.4	Known coagulation disorder i.e. haemophilia, von Willebrand	<input type="checkbox"/> Yes <input type="checkbox"/> No																								
3.5	Previous fibrinogen replacement this admission	<input type="checkbox"/> Yes <input type="checkbox"/> No																								
3.6	Participation in competing study	<input type="checkbox"/> Yes <input type="checkbox"/> No																								
3.7	Randomisation unable to be performed within 6 hours of presentation to hospital	<input type="checkbox"/> Yes <input type="checkbox"/> No																								
If all Inclusion criteria are YES and all Exclusion criteria are NO, patient is eligible for enrolment.																										

FEISTY II CRF

Patient Study ID -

Form 2: Dosing

Instructions:
 Collect all cryo or FC given on this form.
 If dose not given per protocol please complete Form 13 - Protocol Deviation

a) Dose	b) Start of Dose Time and date	c) Trigger for fibrinogen replacement Please tick one
Cryoprecipitate <input type="text"/> <input type="text"/> <input type="text"/> bags OR FC <input type="text"/> <input type="text"/> grams	<input type="checkbox"/> No dose required <input type="checkbox"/> Apheresis <input type="checkbox"/> Pre-Hospital <input type="checkbox"/> No dose required Time: <input type="text"/> : <input type="text"/> Date: <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/>	a) clinician decision <input type="checkbox"/> b) path result <input type="checkbox"/> c) unknown <input type="checkbox"/>
Cryoprecipitate <input type="text"/> <input type="text"/> <input type="text"/> bags OR FC <input type="text"/> <input type="text"/> grams	<input type="checkbox"/> Apheresis <input type="checkbox"/> Pre-Hospital <input type="checkbox"/> No dose required Time: <input type="text"/> : <input type="text"/> Date: <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/>	a) clinician decision <input type="checkbox"/> b) path result <input type="checkbox"/> c) unknown <input type="checkbox"/>
Cryoprecipitate <input type="text"/> <input type="text"/> <input type="text"/> bags OR FC <input type="text"/> <input type="text"/> grams	<input type="checkbox"/> Apheresis <input type="checkbox"/> Pre-Hospital <input type="checkbox"/> No dose required Time: <input type="text"/> : <input type="text"/> Date: <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/>	a) clinician decision <input type="checkbox"/> b) path result <input type="checkbox"/> c) unknown <input type="checkbox"/>
Cryoprecipitate <input type="text"/> <input type="text"/> <input type="text"/> bags OR FC <input type="text"/> <input type="text"/> grams	<input type="checkbox"/> Apheresis <input type="checkbox"/> Pre-Hospital <input type="checkbox"/> No dose required Time: <input type="text"/> : <input type="text"/> Date: <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/>	a) clinician decision <input type="checkbox"/> b) path result <input type="checkbox"/> c) unknown <input type="checkbox"/>
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Cryoprecipitate <input type="text"/> <input type="text"/> <input type="text"/> bags OR FC <input type="text"/> <input type="text"/> grams	<input type="checkbox"/> Apheresis <input type="checkbox"/> Pre-Hospital <input type="checkbox"/> No dose required Time: <input type="text"/> : <input type="text"/> Date: <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/>	a) clinician decision <input type="checkbox"/> b) path result <input type="checkbox"/> c) unknown <input type="checkbox"/>
Cryoprecipitate <input type="text"/> <input type="text"/> <input type="text"/> bags OR FC <input type="text"/> <input type="text"/> grams	<input type="checkbox"/> Apheresis <input type="checkbox"/> Pre-Hospital <input type="checkbox"/> No dose required Time: <input type="text"/> : <input type="text"/> Date: <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/>	a) clinician decision <input type="checkbox"/> b) path result <input type="checkbox"/> c) unknown <input type="checkbox"/>
Cryoprecipitate <input type="text"/> <input type="text"/> <input type="text"/> bags OR FC <input type="text"/> <input type="text"/> grams	<input type="checkbox"/> Apheresis <input type="checkbox"/> Pre-Hospital <input type="checkbox"/> No dose required Time: <input type="text"/> : <input type="text"/> Date: <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/>	a) clinician decision <input type="checkbox"/> b) path result <input type="checkbox"/> c) unknown <input type="checkbox"/>
Cryoprecipitate <input type="text"/> <input type="text"/> <input type="text"/> bags OR FC <input type="text"/> <input type="text"/> grams	<input type="checkbox"/> Apheresis <input type="checkbox"/> Pre-Hospital <input type="checkbox"/> No dose required Time: <input type="text"/> : <input type="text"/> Date: <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/>	a) clinician decision <input type="checkbox"/> b) path result <input type="checkbox"/> c) unknown <input type="checkbox"/>

<h1>FEISTY II CRF</h1>		Patient Study ID <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/>
<h2>Form 4: Hospital and ICU Form including Emergency Department & Operating Theatre</h2>		
4.1 Hospital Admission		
4.1.1 Date and time of hospital admission	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <small>d d m m y y y y</small>	<input style="width: 20px; height: 20px;" type="text"/> : <input style="width: 20px; height: 20px;" type="text"/> <small>h h m m</small>
4.1.2 Date and time of ICU admission	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <small>d d m m y y y y</small>	<input style="width: 20px; height: 20px;" type="text"/> : <input style="width: 20px; height: 20px;" type="text"/> <small>h h m m</small>
4.1.3 Straight to theatre	<input type="checkbox"/> Yes <input type="checkbox"/> No	
4.1.4 Date and time of intubation	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <small>d d m m y y y y</small>	<input style="width: 20px; height: 20px;" type="text"/> : <input style="width: 20px; height: 20px;" type="text"/> <small>h h m m</small>
4.1.5 Date and time of extubation	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <small>d d m m y y y y</small>	<input style="width: 20px; height: 20px;" type="text"/> : <input style="width: 20px; height: 20px;" type="text"/> <small>h h m m</small>
4.1.6 Co-enrolment in another study	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Specify:		
4.1.7 APACHE II Score	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/> N/A
If DISCHARGED / DECEASED, complete Form 8 - Hospital Discharge		
4.2 Glasgow Coma Scale (GCS) earliest available in ED		
4.2.1 Lowest GCS	a) Eye <input style="width: 20px; height: 20px;" type="text"/> /4 b) Verbal <input style="width: 20px; height: 20px;" type="text"/> /5 c) Motor <input style="width: 20px; height: 20px;" type="text"/> /6 OR d) TOTAL <input style="width: 20px; height: 20px;" type="text"/> /15	
4.3 Vital Signs on admission		
4.3.1 Highest HR	a) <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> bpm OR <input type="checkbox"/> not done	
4.3.2 Lowest Sys BP	a) <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> mmHg OR <input type="checkbox"/> not done <input type="checkbox"/> unrecordable	
4.4 Tranexamic Acid		
4.4.1 TXA	<input type="checkbox"/> Yes <input type="checkbox"/> No	
If YES 4.4.1.1 Dose	<input style="width: 20px; height: 20px;" type="text"/> grams	
4.5 Dosage not given (cryoprecipitate/fibrinogen concentrate/riastap)		
4.5.1 NO fibrinogen replacement was given	<input type="checkbox"/>	
If tick box selected you must enter a protocol deviation on form 14 and select 'Dosage not given'		
Continued on following page		

<h1 style="margin: 0;">FEISTY II CRF</h1>		Patient Study ID 	
<h2 style="margin: 0;">Form 5: Blood Product Transfusions Data - first 24 hours</h2>			
a) Date and Time of Transfusion	b) Product Transfused <small>(see table below for codes)</small>	c) Quantity Transfused	d) Measurement
<div style="display: flex; justify-content: space-around;"> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> </div> <div style="display: flex; justify-content: space-around; font-size: 8px;"> d d m m y y h h m m </div>	<input type="checkbox"/> <input type="checkbox"/> pre hospital	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/> bags <input type="checkbox"/> units <input type="checkbox"/> grams
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Product Transfused

- 1 = Packed Red Blood Cells (bags)
- 2 = Fresh Frozen Plasma (bags)
- 3 = Platelets (bags)
- 4 = Prothrombinex (units)

<h1 style="margin: 0;">FEISTY II CRF</h1> <h2 style="margin: 0;">Form 6: Daily Form</h2>		Patient Study ID 	
6.1 Study Day	<input style="width: 30px; height: 20px;" type="text"/>	Study Date	 <small>d d m m y y y y</small>
6.2 Pathology results Collect until day 7 or discharge home whichever occurs first			
Blood	a) Result	b) Time of Blood Result	
6.2.1 Hb	<input style="width: 30px; height: 20px;" type="text"/> g/L OR <input type="checkbox"/> N/A	 <small>d d m m y y y y h h m m</small>	
6.2.2 Platelets	<input style="width: 30px; height: 20px;" type="text"/> $10^9/L$ OR <input type="checkbox"/> N/A	 <small>d d m m y y y y h h m m</small>	
6.2.3 Creatinine	<input style="width: 30px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> $\mu\text{mol/L}$ OR <input type="checkbox"/> N/A	 <small>d d m m y y y y h h m m</small>	
6.2.4 Fibrinogen	<input style="width: 30px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> g/L OR <input type="checkbox"/> N/A <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> FITBEM A5 <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> Clauss Fib	 <small>d d m m y y y y h h m m</small>	
6.3 New Venothromboembolic treatment started			
6.3.1 Anticoagulant	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown		
if yes date started	 <small>d d m m y y y y</small>		
6.3.1.1 Type	<input type="checkbox"/> Heparin <input type="checkbox"/> Low molecular weight heparin		
6.3.1.2 Dose	<input style="width: 30px; height: 20px;" type="text"/> IU <input style="width: 30px; height: 20px;" type="text"/> mg		
6.3.1.3 Frequency per day	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3		
6.3.2 IVC Filter	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown		
if yes date started	 <small>d d m m y y y y</small>		
6.3.3 Pneumatic compression	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown		
if yes date started	 <small>d d m m y y y y</small>		
Continued on following page			

<h1 style="margin: 0;">FEISTY II CRF</h1> <h2 style="margin: 0;">Form 6: Daily continued</h2>		Patient Study ID
6.4 SOFA Score		
6.4.1 PaO ₂	<input style="width: 30px; height: 20px;" type="text"/> mmHg	OR <input type="checkbox"/> N/A
6.4.2 FiO ₂	<input style="width: 30px; height: 20px;" type="text"/> %	OR <input type="checkbox"/> N/A
6.4.3 Lowest platelets	<input style="width: 30px; height: 20px;" type="text"/> ×10 ⁹ /L	OR <input type="checkbox"/> N/A
6.4.4 Highest bilirubin (total)	<input style="width: 30px; height: 20px;" type="text"/> <input type="checkbox"/> μmol/L <input type="checkbox"/> mg/dL	OR <input type="checkbox"/> N/A
6.4.5 Highest GCS	a) Eye <input style="width: 20px; height: 20px;" type="text"/> /4 b) Verbal <input style="width: 20px; height: 20px;" type="text"/> /5 c) Motor <input style="width: 20px; height: 20px;" type="text"/> /6 OR d) TOTAL <input style="width: 20px; height: 20px;" type="text"/> /15	
6.4.6 Level of hypotension	<input type="checkbox"/> MAP ≥ 70 mmHg [0] <input type="checkbox"/> MAP < 70 mmHg [1] <input type="checkbox"/> Dopamine ≤ 5 μg/kg/min or Dobutamine (any dose) [2] <input type="checkbox"/> Dopamine 6 – 15 μg/kg/min or Adrenaline ≤ 0.1 μg/kg/min or Noradrenaline ≤ 0.1 μg/kg/min [3] <input type="checkbox"/> Dopamine > 15 μg/kg/min or Adrenaline > 0.1 μg/kg/min or Noradrenaline > 0.1 μg/kg/min [4]	
6.4.7 Highest creatinine	<input type="checkbox"/> < 1.2 mg/dL (< 110 μmol/L) or N/A [0] <input type="checkbox"/> 1.2 – 1.9 mg/dL (110 – 170 μmol/L) [1] <input type="checkbox"/> 2.0 – 3.4 mg/dL (171 – 299 μmol/L) [2] <input type="checkbox"/> 3.5 – 4.9 mg/dL (300 – 440 μmol/L) [3] <input type="checkbox"/> ≥ 5mg/dL (≥ 440 μmol/L) [4]	
6.4.8 Total urine output	<input type="checkbox"/> ≥ 500ml/day or N/A (score is based on creatinine) [0] <input type="checkbox"/> 200 – 499 ml/day [3] <input type="checkbox"/> < 200ml/day [4]	

FEISTY II CRF		Patient Study ID <input style="width: 40px; height: 20px;" type="text"/> - <input style="width: 40px; height: 20px;" type="text"/>			
Form 7: Pre-injury WHODAS					
7.1 Pre-injury WHODAS 2.0					
7.1.1 Was the pre-injury WHODAS 2.0 completed	<input type="checkbox"/> Yes <input type="checkbox"/> No				
7.1.2 Person completing WHODAS 2.0	<input type="checkbox"/> Participant <input type="checkbox"/> Proxy				
7.1.3 Date of pre-injury WHODAS 2.0	<input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <small>d d m m y y y y</small>				
In the past 30 days, how much difficulty did your relative have doing the following activities: (Note: the questionnaire uses the term 'relative' to mean friend, 'relative' or 'carer'. Please choose one response.)					
(For each question, check one)	NONE	MILD	MODERATE	SEVERE	EXTREME OR CANNOT DO
7.1.4 Standing for long periods such as 30 minutes?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.1.5 Taking care of his or her household responsibilities?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.1.6 Learning a new task, for example learning to get to a new place?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.1.7 How much of a problem did your relative have joining in community activities (for example festivities, religious or other activities) in the same way as anyone else can?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.1.8 How much has your relative been emotionally affected by his or her health problems?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.1.9 Concentrating on doing something for ten minutes?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.1.10 Walking long distance such as kilometre or equivalent?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.1.11 Washing his or her whole body?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.1.12 Getting dressed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.1.13 Dealing with people he or she does not know?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.1.14 Maintaining a friendship?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.1.15 His or her day-to-day work or school?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.1.16 Overall in the past 30 days, how many day were these difficulties present?	<input style="width: 40px; height: 20px;" type="text"/>				
7.1.17 In the past 30 days, for how many days was your relative totally unable to carry out their usual activities or work because of any health condition?	<input style="width: 40px; height: 20px;" type="text"/>				
7.1.18 In the past 30 days, not counting the days that your relative was totally unable, for how many days did your relative cut back or reduce their usual activities or work because of any health conditions?	<input style="width: 40px; height: 20px;" type="text"/>				

FEISTY II CRF		Patient Study ID <input style="width: 40px; height: 20px;" type="text"/> - <input style="width: 40px; height: 20px;" type="text"/>
Form 8: Discharge		
8.1 Hospital Discharge		
8.1.1 Date and time of ICU discharge	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> · <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> · <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> : <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> : <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	<input type="checkbox"/> N/A
8.1.2 Vital status at ICU discharge	<input type="checkbox"/> Alive <input type="checkbox"/> Deceased If deceased go to 8.1.4.2	<input type="checkbox"/> N/A
8.1.3 Hospital discharge date and time	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> · <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> · <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> : <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> : <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	
8.1.4 Vital status at hospital discharge	<input type="checkbox"/> Alive <input type="checkbox"/> Deceased	
8.1.4.1 Discharge destination	<input type="checkbox"/> Home <input type="checkbox"/> Long term care facility <input type="checkbox"/> Other acute hospital <input type="checkbox"/> Rehab centre <input type="checkbox"/> Other If OTHER specify <input style="width: 280px; height: 20px;" type="text"/>	
If DECEASED		
8.1.4.2 Date and time of death	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> · <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> · <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> : <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> : <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	
8.1.4.3 Primary cause (select one)	<input type="checkbox"/> Exsanguination <input type="checkbox"/> Vascular occlusion <input type="checkbox"/> Stroke <input type="checkbox"/> Pulmonary Embolism <input type="checkbox"/> Acute myocardial infarction <input type="checkbox"/> Multi organ failure <input type="checkbox"/> Head injury <input type="checkbox"/> Other If OTHER specify <input style="width: 280px; height: 20px;" type="text"/>	
8.2 Injury Severity Score (ISS)		
Enter the ISS score from the hospital trauma registry or trauma service		
8.2.1 Injury Severity Score	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	
8.3 Abbreviated Injury Scale (AIS)		
Maximal Abbreviated Injury Scale (AIS) for each body region (score from 0 to 6)		
8.3.1 Head or neck	<input style="width: 20px; height: 20px;" type="text"/> /6	8.3.2 Face
8.3.4 Abdomen or pelvic contents	<input style="width: 20px; height: 20px;" type="text"/> /6	8.3.5 Extremities or pelvic girdle
		8.3.3 Chest
		8.3.6 External

<h1 style="margin: 0;">FEISTY II CRF</h1> <h2 style="margin: 0;">Form 9: 90 Day Follow-up</h2>		Patient Study ID 																								
9.1 Vital Status																										
9.1.1 Date of 90 day follow-up	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 20px; text-align: center;"> </td> <td style="border: 1px solid black; width: 20px; text-align: center;"> </td> <td style="border: 1px solid black; width: 20px; text-align: center;"> </td> <td style="border: 1px solid black; width: 20px; text-align: center;"> </td> <td style="border: 1px solid black; width: 20px; text-align: center;"> </td> <td style="border: 1px solid black; width: 20px; text-align: center;"> </td> <td style="border: 1px solid black; width: 20px; text-align: center;"> </td> <td style="border: 1px solid black; width: 20px; text-align: center;"> </td> </tr> <tr> <td style="text-align: center; font-size: 8px;">d</td> <td style="text-align: center; font-size: 8px;">d</td> <td style="text-align: center; font-size: 8px;">m</td> <td style="text-align: center; font-size: 8px;">m</td> <td style="text-align: center; font-size: 8px;">y</td> <td style="text-align: center; font-size: 8px;">y</td> <td style="text-align: center; font-size: 8px;">y</td> <td style="text-align: center; font-size: 8px;">y</td> </tr> </table>										d	d	m	m	y	y	y	y								
d	d	m	m	y	y	y	y																			
9.1.2 If follow up not completed, give reason	<input type="checkbox"/> Patient lost follow-up <input type="checkbox"/> Alive but refused consent to follow-up <input type="checkbox"/> Alive but unable to follow-up for other reasons. Please specify 																									
9.1.3 Has the patient been discharged from hospital?	<input type="checkbox"/> Yes <input type="checkbox"/> No 																									
If YES 9.1.3.1 Has the patient been readmitted to hospital?	<input type="checkbox"/> Yes <input type="checkbox"/> No																									
9.1.4 Mortality at 90 day follow-up	<input type="checkbox"/> Alive <input type="checkbox"/> Deceased																									
If ALIVE																										
9.1.4.1 What is the patient's location at 90 days (select one)	<table style="width: 100%; border-collapse: collapse;"> <tr> <td><input type="checkbox"/> Hospital</td> <td><input type="checkbox"/> Long term care facility</td> </tr> <tr> <td><input type="checkbox"/> Rehab centre</td> <td><input type="checkbox"/> Other acute hospital</td> </tr> <tr> <td><input type="checkbox"/> Home</td> <td><input type="checkbox"/> Unknown</td> </tr> <tr> <td colspan="2"><input type="checkbox"/> Other If OTHER, specify </td> </tr> </table>		<input type="checkbox"/> Hospital	<input type="checkbox"/> Long term care facility	<input type="checkbox"/> Rehab centre	<input type="checkbox"/> Other acute hospital	<input type="checkbox"/> Home	<input type="checkbox"/> Unknown	<input type="checkbox"/> Other If OTHER, specify 																	
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<input type="checkbox"/> Other If OTHER, specify 																										
If DECEASED																										
9.1.4.2 Date and time of death	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 20px; text-align: center;"> </td> <td style="border: 1px solid black; width: 20px; text-align: center;"> </td> <td style="border: 1px solid black; width: 20px; text-align: center;"> </td> <td style="border: 1px solid black; width: 20px; text-align: center;"> </td> <td style="border: 1px solid black; width: 20px; text-align: center;"> </td> <td style="border: 1px solid black; width: 20px; text-align: center;"> </td> <td style="border: 1px solid black; width: 20px; text-align: center;"> </td> <td style="border: 1px solid black; width: 20px; text-align: center;"> </td> <td style="border: 1px solid black; width: 20px; text-align: center;"> </td> <td style="border: 1px solid black; width: 20px; text-align: center;"> </td> <td style="border: 1px solid black; width: 20px; text-align: center;"> </td> <td style="border: 1px solid black; width: 20px; text-align: center;"> </td> </tr> <tr> <td style="text-align: center; font-size: 8px;">d</td> <td style="text-align: center; font-size: 8px;">d</td> <td style="text-align: center; font-size: 8px;">m</td> <td style="text-align: center; font-size: 8px;">m</td> <td style="text-align: center; font-size: 8px;">y</td> <td style="text-align: center; font-size: 8px;">y</td> <td style="text-align: center; font-size: 8px;">y</td> <td style="text-align: center; font-size: 8px;">y</td> <td style="text-align: center; font-size: 8px;">h</td> <td style="text-align: center; font-size: 8px;">h</td> <td style="text-align: center; font-size: 8px;">m</td> <td style="text-align: center; font-size: 8px;">m</td> </tr> </table>														d	d	m	m	y	y	y	y	h	h	m	m
d	d	m	m	y	y	y	y	h	h	m	m															
9.1.4.3 Primary cause (select one)	<table style="width: 100%; border-collapse: collapse;"> <tr> <td><input type="checkbox"/> Exsanguination</td> <td><input type="checkbox"/> Pulmonary embolism</td> </tr> <tr> <td><input type="checkbox"/> Stroke</td> <td><input type="checkbox"/> Acute myocardial infarction</td> </tr> <tr> <td><input type="checkbox"/> Multi organ failure</td> <td><input type="checkbox"/> Head injury</td> </tr> <tr> <td><input type="checkbox"/> Vascular occlusion</td> <td><input type="checkbox"/> Unknown</td> </tr> <tr> <td colspan="2"><input type="checkbox"/> Other If OTHER, specify </td> </tr> </table>		<input type="checkbox"/> Exsanguination	<input type="checkbox"/> Pulmonary embolism	<input type="checkbox"/> Stroke	<input type="checkbox"/> Acute myocardial infarction	<input type="checkbox"/> Multi organ failure	<input type="checkbox"/> Head injury	<input type="checkbox"/> Vascular occlusion	<input type="checkbox"/> Unknown	<input type="checkbox"/> Other If OTHER, specify 															
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<input type="checkbox"/> Vascular occlusion	<input type="checkbox"/> Unknown																									
<input type="checkbox"/> Other If OTHER, specify 																										
9.1.4.4 What was the patient's location at time of death (select one)	<table style="width: 100%; border-collapse: collapse;"> <tr> <td><input type="checkbox"/> Hospital</td> <td><input type="checkbox"/> Long term care facility</td> </tr> <tr> <td><input type="checkbox"/> Rehab centre</td> <td><input type="checkbox"/> Other acute hospital</td> </tr> <tr> <td><input type="checkbox"/> Home</td> <td><input type="checkbox"/> Unknown</td> </tr> <tr> <td colspan="2"><input type="checkbox"/> Other If OTHER, specify </td> </tr> </table>		<input type="checkbox"/> Hospital	<input type="checkbox"/> Long term care facility	<input type="checkbox"/> Rehab centre	<input type="checkbox"/> Other acute hospital	<input type="checkbox"/> Home	<input type="checkbox"/> Unknown	<input type="checkbox"/> Other If OTHER, specify 																	
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<input type="checkbox"/> Other If OTHER, specify 																										
9.1.5 Comments (brief description of injury circumstances/all injuries/helpful comments about patient)	<div style="border: 1px solid black; height: 60px; width: 100%;"></div>																									
Continued on following page																										

FEISTY II CRF

Patient Study ID -

Form 9: 90 Day Follow-up continued

9.2 Level of Care Information (after hospital discharge)

9.2.1 Please list admissions in chronological order according to the following facility codes:

- 1 - Rehabilitation centre 2 - Acute care hospital 3 - Long-term HIGH level care facility
 4 - Transitional living centre 5 - Long-term LOW level care facility 6 - Other, specify:.....

Date of admission e.g 01/06/2022	Date of discharge	Facility code	Not discharged
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<h1 style="margin: 0;">FEISTY II CRF</h1> <h2 style="margin: 0;">Form 9: 90 Day Follow-up continued</h2>		Patient Study ID 																
9.3 Pre-injury WHODAS 2.0 (Note: complete only for participants who did not have a pre-injury WHODAS 2.0 completed during the index admission)																		
9.3.1	Was the pre-injury WHODAS 2.0 completed at 90 Day Follow-up	<input type="checkbox"/> Yes <input type="checkbox"/> No																
9.3.2	Person completing WHODAS 2.0	<input type="checkbox"/> Participant <input type="checkbox"/> Proxy																
9.3.3	Date of pre-injury WHODAS 2.0	<table style="border-collapse: collapse; margin: 0 auto;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> </tr> <tr> <td style="text-align: center; font-size: 8px;">d</td> <td style="text-align: center; font-size: 8px;">d</td> <td style="text-align: center; font-size: 8px;">m</td> <td style="text-align: center; font-size: 8px;">m</td> <td style="text-align: center; font-size: 8px;">y</td> <td style="text-align: center; font-size: 8px;">y</td> <td style="text-align: center; font-size: 8px;">y</td> <td style="text-align: center; font-size: 8px;">y</td> </tr> </table>									d	d	m	m	y	y	y	y
d	d	m	m	y	y	y	y											
In the past 30 days, how much difficulty did your relative have doing the following activities: (Note: the questionnaire uses the term 'relative' to mean friend, 'relative' or 'carer'. Please choose one response.)																		
(For each question, check one)																		
		NONE MILD MODERATE SEVERE EXTREME OR CANNOT DO																
9.3.4	Standing for long periods such periods such as 30 minutes?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>																
9.3.5	Taking care of his or her households responsibilities?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>																
9.3.6	Learning a new task, for example learning to get to a new place?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>																
9.3.7	How much of a problem did your relative have joining in community activities (for example festivities, religious or other activities) in the same way as anyone else can?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>																
9.3.8	How much has your relative been emotionally affected by his or her health problems?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>																
9.3.9	Concentrating on doing something for ten minutes?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>																
9.3.10	Walking long distance such as kilometre or equivalent?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>																
9.3.11	Washing his or her whole body?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>																
9.3.12	Getting dressed?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>																
9.3.13	Dealing with people he or she does not know?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>																
9.3.14	Maintaining a friendship?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>																
9.3.15	His or her day-to-day work or school?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>																
9.3.16	Overall in the past 30 days, how many day were these difficulties present?	<table style="border-collapse: collapse; margin: 0 auto;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> </tr> </table>																
9.3.17	In the past 30 days, for how many days was your relative totally unable to carry out their usual activities or work because of any health condition?	<table style="border-collapse: collapse; margin: 0 auto;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> </tr> </table>																
9.3.18	In the past 30 days, not counting the days that your relative was totally unable, for how many days did your relative cut back or reduce their usual activities or work because of any health conditions?	<table style="border-collapse: collapse; margin: 0 auto;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> </tr> </table>																

<h1 style="margin: 0;">FEISTY II CRF</h1> <h2 style="margin: 0;">Form 9: 90 Day Follow-up continued</h2>		Patient Study ID <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>																
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9.4.2	Date of WHODAS 2.0	<table style="border-collapse: collapse; margin: auto;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> </tr> <tr> <td style="text-align: center; font-size: 8px;">d</td> <td style="text-align: center; font-size: 8px;">d</td> <td style="text-align: center; font-size: 8px;">m</td> <td style="text-align: center; font-size: 8px;">m</td> <td style="text-align: center; font-size: 8px;">y</td> <td style="text-align: center; font-size: 8px;">y</td> <td style="text-align: center; font-size: 8px;">y</td> <td style="text-align: center; font-size: 8px;">y</td> </tr> </table>									d	d	m	m	y	y	y	y
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(For each question, check one)		<table style="width: 100%; text-align: center; border-collapse: collapse;"> <tr> <td style="width: 15%;"></td> <td style="width: 15%;">NONE</td> <td style="width: 15%;">MILD</td> <td style="width: 15%;">MODERATE</td> <td style="width: 15%;">SEVERE</td> <td style="width: 15%;">EXTREME OR CANNOT DO</td> </tr> </table>		NONE	MILD	MODERATE	SEVERE	EXTREME OR CANNOT DO										
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9.4.4	Taking care of his or her household responsibilities?	<table style="width: 100%; text-align: center; border-collapse: collapse;"> <tr> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> </tr> </table>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>										
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9.4.5	Learning a new task, for example learning to get to a new place?	<table style="width: 100%; text-align: center; border-collapse: collapse;"> <tr> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> </tr> </table>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>										
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9.4.8	Concentrating on doing something for ten minutes?	<table style="width: 100%; text-align: center; border-collapse: collapse;"> <tr> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> </tr> </table>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>										
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9.4.9	Walking long distance such as kilometre or equivalent?	<table style="width: 100%; text-align: center; border-collapse: collapse;"> <tr> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> </tr> </table>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>										
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>													
9.4.10	Washing his or her whole body?	<table style="width: 100%; text-align: center; border-collapse: collapse;"> <tr> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> </tr> </table>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>										
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>													
9.4.11	Getting dressed?	<table style="width: 100%; text-align: center; border-collapse: collapse;"> <tr> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> </tr> </table>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>										
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9.4.12	Dealing with people he or she does not know?	<table style="width: 100%; text-align: center; border-collapse: collapse;"> <tr> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> </tr> </table>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>										
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9.4.13	Maintaining a friendship?	<table style="width: 100%; text-align: center; border-collapse: collapse;"> <tr> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> </tr> </table>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>										
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9.4.14	His or her day-to-day work or school?	<table style="width: 100%; text-align: center; border-collapse: collapse;"> <tr> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> </tr> </table>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>										
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9.4.15	Overall in the past 30 days, how many days were these difficulties present?	<table style="width: 100%; text-align: center; border-collapse: collapse;"> <tr> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> <td style="width: 15%;"><input type="checkbox"/></td> </tr> </table>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>										
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9.4.16	In the past 30 days, for how many days was your relative totally unable to carry out their usual activities or work because of any health condition?	<table style="width: 100%; text-align: center; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px; border: 1px solid black;"></td> <td style="width: 20px; height: 20px; border: 1px solid black;"></td> </tr> </table>																
9.4.17	In the past 30 days, not counting the days that your relative was totally unable, for how many days did your relative cut back or reduce their usual activities or work because of any health conditions?	<table style="width: 100%; text-align: center; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px; border: 1px solid black;"></td> <td style="width: 20px; height: 20px; border: 1px solid black;"></td> </tr> </table>																

FEISTY II CRF

Patient Study ID

Form 9: 90 Day Follow-up continued

9.5 EQ-5D

Please select ONE option that best describes your health TODAY

If NOT DONE please select this under drop down on the FEISTY II database

- 9.5.1 Mobility:
- You have no problems with walking around
 - You have slight problems with walking around
 - You have moderate problems with walking around
 - You have severe problems with walking around
 - You are unable to walk around
- 9.5.2 Personal Care:
- You have no problems with washing or dressing yourself
 - You have slight problems with washing or dressing yourself
 - You have moderate problems with washing or dressing yourself
 - You have severe problems with washing or dressing yourself
 - You are unable to wash or dress yourself
- 9.5.3 Usual activities:
- You have no problems doing your usual activities
 - You have slight problems doing your usual activities
 - You have moderate problems doing your usual activities
 - You have severe problems doing your usual activities
 - You are unable to do your usual activities
- 9.5.4 Pain/discomfort:
- You have no pain or discomfort
 - You have slight pain or discomfort
 - You have moderate problems doing your usual activities
 - You have severe pain or discomfort
 - You have extreme pain or discomfort
- 9.5.5 Anxiety/depression:
- You are not anxious or depressed
 - You are slightly anxious or depressed
 - You are moderately anxious or depressed
 - You are severely anxious or depressed
 - You are extremely anxious or depressed

FEISTY II CRF

Patient Study ID

Form 9: 90 Day Follow-up continued

9.6 EQ-VAS

I would now like you to indicate how good or bad your health state is today on a scale of 0-100, with 0 being the 'worst imaginable health state' and 100 being the 'best imaginable health state'.

If NOTE DONE please select this on the FEISTY II database.

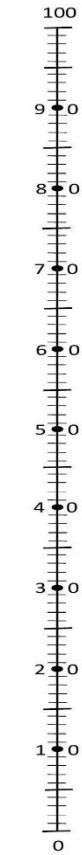
9.6.1 Pre injury score / 100

9.6.2 Health state today / 100

Not done

Not done

Best imaginable health state



Worst imaginable health state

Best imaginable health state



Worst imaginable health state

<h1 style="margin: 0;">FEISTY II CRF</h1> <h2 style="margin: 0;">Form 10: 180 Day Follow-up</h2>		Patient Study ID 																								
10.1 Vital Status																										
10.1.1 Date of 180 day follow-up	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> </tr> <tr> <td style="text-align: center; font-size: 8px;">d</td> <td style="text-align: center; font-size: 8px;">d</td> <td style="text-align: center; font-size: 8px;">m</td> <td style="text-align: center; font-size: 8px;">m</td> <td style="text-align: center; font-size: 8px;">y</td> <td style="text-align: center; font-size: 8px;">y</td> <td style="text-align: center; font-size: 8px;">y</td> <td style="text-align: center; font-size: 8px;">y</td> </tr> </table>										d	d	m	m	y	y	y	y								
d	d	m	m	y	y	y	y																			
10.1.2 If follow up not completed, give reason	<input type="checkbox"/> Patient lost follow-up <input type="checkbox"/> Alive but refused consent to follow-up <input type="checkbox"/> Alive but unable to follow-up for other reasons. Please specify 																									
10.1.3 Has the patient been discharged from hospital since 90 day follow-up?	<input type="checkbox"/> Yes <input type="checkbox"/> No																									
If YES																										
10.1.3.1 Has the patient been readmitted to hospital?	<input type="checkbox"/> Yes <input type="checkbox"/> No																									
10.1.4 Mortality at 180 day follow-up	<input type="checkbox"/> Alive <input type="checkbox"/> Deceased																									
If ALIVE																										
10.1.4.1 What is the patient's location at 180 days (select one)	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;"><input type="checkbox"/> Hospital</td> <td style="width: 50%;"><input type="checkbox"/> Long term care facility</td> </tr> <tr> <td><input type="checkbox"/> Rehab centre</td> <td><input type="checkbox"/> Other acute hospital</td> </tr> <tr> <td><input type="checkbox"/> Home</td> <td><input type="checkbox"/> Unknown</td> </tr> <tr> <td colspan="2"><input type="checkbox"/> Other If OTHER, specify </td> </tr> </table>		<input type="checkbox"/> Hospital	<input type="checkbox"/> Long term care facility	<input type="checkbox"/> Rehab centre	<input type="checkbox"/> Other acute hospital	<input type="checkbox"/> Home	<input type="checkbox"/> Unknown	<input type="checkbox"/> Other If OTHER, specify 																	
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If DECEASED																										
10.1.4.2 Date and time of death	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> </tr> <tr> <td style="text-align: center; font-size: 8px;">d</td> <td style="text-align: center; font-size: 8px;">d</td> <td style="text-align: center; font-size: 8px;">m</td> <td style="text-align: center; font-size: 8px;">m</td> <td style="text-align: center; font-size: 8px;">y</td> <td style="text-align: center; font-size: 8px;">y</td> <td style="text-align: center; font-size: 8px;">y</td> <td style="text-align: center; font-size: 8px;">y</td> <td style="text-align: center; font-size: 8px;">h</td> <td style="text-align: center; font-size: 8px;">h</td> <td style="text-align: center; font-size: 8px;">m</td> <td style="text-align: center; font-size: 8px;">m</td> </tr> </table>														d	d	m	m	y	y	y	y	h	h	m	m
d	d	m	m	y	y	y	y	h	h	m	m															
10.1.4.3 Primary cause (select one)	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;"><input type="checkbox"/> Exsanguination</td> <td style="width: 50%;"><input type="checkbox"/> Pulmonary embolism</td> </tr> <tr> <td><input type="checkbox"/> Stroke</td> <td><input type="checkbox"/> Acute myocardial infarction</td> </tr> <tr> <td><input type="checkbox"/> Multi organ failure</td> <td><input type="checkbox"/> Head injury</td> </tr> <tr> <td><input type="checkbox"/> Vascular occlusion</td> <td><input type="checkbox"/> Unknown</td> </tr> <tr> <td colspan="2"><input type="checkbox"/> Other If OTHER, specify </td> </tr> </table>		<input type="checkbox"/> Exsanguination	<input type="checkbox"/> Pulmonary embolism	<input type="checkbox"/> Stroke	<input type="checkbox"/> Acute myocardial infarction	<input type="checkbox"/> Multi organ failure	<input type="checkbox"/> Head injury	<input type="checkbox"/> Vascular occlusion	<input type="checkbox"/> Unknown	<input type="checkbox"/> Other If OTHER, specify 															
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<input type="checkbox"/> Other If OTHER, specify 																										
10.1.4.4 What was the patient's location at time of death (select one)	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;"><input type="checkbox"/> Hospital</td> <td style="width: 50%;"><input type="checkbox"/> Long term care facility</td> </tr> <tr> <td><input type="checkbox"/> Rehab centre</td> <td><input type="checkbox"/> Other acute hospital</td> </tr> <tr> <td><input type="checkbox"/> Home</td> <td><input type="checkbox"/> Unknown</td> </tr> <tr> <td colspan="2"><input type="checkbox"/> Other If OTHER, specify </td> </tr> </table>		<input type="checkbox"/> Hospital	<input type="checkbox"/> Long term care facility	<input type="checkbox"/> Rehab centre	<input type="checkbox"/> Other acute hospital	<input type="checkbox"/> Home	<input type="checkbox"/> Unknown	<input type="checkbox"/> Other If OTHER, specify 																	
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10.1.5 Comments (brief description of injury circumstances/all injuries/helpful comments about patient)	<div style="border: 1px solid black; height: 60px; width: 100%;"></div>																									
Continued on following page																										

<h1 style="margin: 0;">FEISTY II CRF</h1> <h2 style="margin: 0;">Form 10: 180 Day Follow-up continued</h2>		Patient Study ID <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/>			
10.2 WHODAS 2.0					
10.2.1 Person completing WHODAS 2.0	<input type="checkbox"/> Participant <input type="checkbox"/> Proxy				
10.2.2 Date of WHODAS 2.0	<input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <small style="display: flex; justify-content: space-around; font-size: 8px;"> d d m m y y y y </small>				
In the past 30 days, how much difficulty did your relative have doing the following activities: (Note: the questionnaire uses the term 'relative' to mean friend, 'relative' or 'carer'. Please choose one response.)					
(For each question, check one)	NONE	MILD	MODERATE	SEVERE	EXTREME OR CANNOT DO
10.2.3 Standing for long periods such as 30 minutes?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.2.4 Taking care of his or her household responsibilities?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.2.5 Learning a new task, for example learning to get to a new place?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.2.6 How much of a problem did your relative have joining in community activities (for example festivities, religious or other activities) in the same way as anyone else can?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.2.7 How much has your relative been emotionally affected by his or her health problems?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.2.8 Concentrating on doing something for ten minutes?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.2.9 Walking long distance such as kilometre or equivalent?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.2.10 Washing his or her whole body?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.2.11 Getting dressed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.2.12 Dealing with people he or she does not know?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.2.13 Maintaining a friendship?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.2.14 His or her day-to-day work or school?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.2.15 Overall in the past 30 days, how many days were these difficulties present?	<input style="width: 40px; height: 20px;" type="text"/>				
10.2.16 In the past 30 days, for how many days was your relative totally unable to carry out their usual activities or work because of any health condition?	<input style="width: 40px; height: 20px;" type="text"/>				
10.2.17 In the past 30 days, not counting the days that your relative was totally unable, for how many days did your relative cut back or reduce their usual activities or work because of any health conditions?	<input style="width: 40px; height: 20px;" type="text"/>				

FEISTY II CRF

Patient Study ID

Form 10: 180 Day Follow-up continued

10.3 EQ-5D

Please select ONE option that best describes your health TODAY

If NOT DONE please select this from the dropdown menu on the FEISTY II database.

10.3.1 Mobility:

- You have no problems with walking around
- You have slight problems with walking around
- You have moderate problems with walking around
- You have severe problems with walking around
- You are unable to walk around

10.3.2 Personal Care:

- You have no problems with washing or dressing yourself
- You have slight problems with washing or dressing yourself
- You have moderate problems with washing or dressing yourself
- You have severe problems with washing or dressing yourself
- You are unable to wash or dress yourself

10.3.3 Usual activities:

- You have no problems doing your usual activities
- You have slight problems doing your usual activities
- You have moderate problems doing your usual activities
- You have severe problems doing your usual activities
- You are unable to do your usual activities

10.3.4 Pain/discomfort:

- You have no pain or discomfort
- You have slight pain or discomfort
- You have moderate problems doing your usual activities
- You have severe pain or discomfort
- You have extreme pain or discomfort

10.3.5 Anxiety/depression:

- You are not anxious or depressed
- You are slightly anxious or depressed
- You are moderately anxious or depressed
- You are severely anxious or depressed
- You are extremely anxious or depressed

FEISTY II CRF

Patient Study ID

Form 10: 180 Day Follow-up continued

10.4 EQ-VAS

I would now like you to indicate how good or bad your health state is today on a scale of 0-100, with 0 being the 'worst imaginable health state' and 100 being the 'best imaginable health state'.

10.4.1 Health state today / 100

Not done

Best imaginable health state



Worst imaginable health state

FEISTY II CRF		Patient Study ID <input style="width: 40px; height: 20px;" type="text"/> - <input style="width: 40px; height: 20px;" type="text"/>										
Form 11: 12 Month Follow-up												
11.1 Vital Status												
11.1.1 Date of 12 month follow-up	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> · <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> · <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <small>d d m m y y y y</small>											
11.1.2 If follow up not completed, give reason	<input type="checkbox"/> Patient lost follow-up <input type="checkbox"/> Alive but refused consent to follow-up <input type="checkbox"/> Alive but unable to follow-up for other reasons. Please specify <div style="border: 1px solid black; height: 20px; width: 100%; margin-top: 5px;"></div>											
11.1.3 Has the patient been discharged from hospital since 180 day follow-up?	<input type="checkbox"/> Yes <input type="checkbox"/> No											
If YES	11.1.3.1 Has the patient been readmitted to hospital? <input type="checkbox"/> Yes <input type="checkbox"/> No											
11.1.4 Mortality 12 month follow-up	<input type="checkbox"/> Alive <input type="checkbox"/> Deceased											
If ALIVE	11.1.4.1 What is the patient's location at 12 months (select one) <table style="width: 100%; border: none;"> <tr> <td><input type="checkbox"/> Hospital</td> <td><input type="checkbox"/> Long term care facility</td> </tr> <tr> <td><input type="checkbox"/> Rehab centre</td> <td><input type="checkbox"/> Other acute hospital</td> </tr> <tr> <td><input type="checkbox"/> Home</td> <td><input type="checkbox"/> Unknown</td> </tr> <tr> <td colspan="2"><input type="checkbox"/> Other If OTHER, specify <div style="border: 1px solid black; width: 100%; height: 20px; margin-top: 5px;"></div></td> </tr> </table>		<input type="checkbox"/> Hospital	<input type="checkbox"/> Long term care facility	<input type="checkbox"/> Rehab centre	<input type="checkbox"/> Other acute hospital	<input type="checkbox"/> Home	<input type="checkbox"/> Unknown	<input type="checkbox"/> Other If OTHER, specify <div style="border: 1px solid black; width: 100%; height: 20px; margin-top: 5px;"></div>			
<input type="checkbox"/> Hospital	<input type="checkbox"/> Long term care facility											
<input type="checkbox"/> Rehab centre	<input type="checkbox"/> Other acute hospital											
<input type="checkbox"/> Home	<input type="checkbox"/> Unknown											
<input type="checkbox"/> Other If OTHER, specify <div style="border: 1px solid black; width: 100%; height: 20px; margin-top: 5px;"></div>												
If DECEASED	11.1.4.2 Date and time of death <table style="width: 100%; border: none;"> <tr> <td style="width: 60%;"> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> · <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> · <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <small>d d m m y y y y</small> </td> <td style="width: 40%;"> <input style="width: 20px; height: 20px;" type="text"/> : <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <small>h h m m</small> </td> </tr> </table>		<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> · <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> · <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <small>d d m m y y y y</small>	<input style="width: 20px; height: 20px;" type="text"/> : <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <small>h h m m</small>								
<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> · <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> · <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <small>d d m m y y y y</small>	<input style="width: 20px; height: 20px;" type="text"/> : <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <small>h h m m</small>											
11.1.4.3 Primary cause (select one)	<table style="width: 100%; border: none;"> <tr> <td><input type="checkbox"/> Exsanguination</td> <td><input type="checkbox"/> Pulmonary embolism</td> </tr> <tr> <td><input type="checkbox"/> Stroke</td> <td><input type="checkbox"/> Acute myocardial infarction</td> </tr> <tr> <td><input type="checkbox"/> Multi organ failure</td> <td><input type="checkbox"/> Head injury</td> </tr> <tr> <td><input type="checkbox"/> Vascular occlusion</td> <td><input type="checkbox"/> Unknown</td> </tr> <tr> <td colspan="2"><input type="checkbox"/> Other If OTHER, specify <div style="border: 1px solid black; width: 100%; height: 20px; margin-top: 5px;"></div></td> </tr> </table>		<input type="checkbox"/> Exsanguination	<input type="checkbox"/> Pulmonary embolism	<input type="checkbox"/> Stroke	<input type="checkbox"/> Acute myocardial infarction	<input type="checkbox"/> Multi organ failure	<input type="checkbox"/> Head injury	<input type="checkbox"/> Vascular occlusion	<input type="checkbox"/> Unknown	<input type="checkbox"/> Other If OTHER, specify <div style="border: 1px solid black; width: 100%; height: 20px; margin-top: 5px;"></div>	
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11.1.4.4 What was the patient's location at time of death (select one)	<table style="width: 100%; border: none;"> <tr> <td><input type="checkbox"/> Hospital</td> <td><input type="checkbox"/> Long term care facility</td> </tr> <tr> <td><input type="checkbox"/> Rehab centre</td> <td><input type="checkbox"/> Other acute hospital</td> </tr> <tr> <td><input type="checkbox"/> Home</td> <td><input type="checkbox"/> Unknown</td> </tr> <tr> <td colspan="2"><input type="checkbox"/> Other If OTHER, specify <div style="border: 1px solid black; width: 100%; height: 20px; margin-top: 5px;"></div></td> </tr> </table>		<input type="checkbox"/> Hospital	<input type="checkbox"/> Long term care facility	<input type="checkbox"/> Rehab centre	<input type="checkbox"/> Other acute hospital	<input type="checkbox"/> Home	<input type="checkbox"/> Unknown	<input type="checkbox"/> Other If OTHER, specify <div style="border: 1px solid black; width: 100%; height: 20px; margin-top: 5px;"></div>			
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11.1.5 Comments (brief description of injury circumstances/all injuries/helpful comments about patient)	<div style="border: 1px solid black; height: 60px; width: 100%; margin-top: 10px;"></div>											
Continued on following page												

<h1 style="margin: 0;">FEISTY II CRF</h1> <h2 style="margin: 0;">Form 11: 12 Month Follow-up continued</h2>		Patient Study ID <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/>			
11.2 WHODAS 2.0					
11.2.1 Person completing WHODAS 2.0	<input type="checkbox"/> Participant <input type="checkbox"/> Proxy				
11.2.2 Date of WHODAS 2.0	<input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <small style="display: flex; justify-content: space-around; font-size: 8px;"> d d m m y y y y </small>				
In the past 30 days, how much difficulty did your relative have doing the following activities: (Note: the questionnaire uses the term 'relative' to mean friend, 'relative' or 'carer'. Please choose one response.)					
(For each question, check one)	NONE	MILD	MODERATE	SEVERE	EXTREME OR CANNOT DO
11.2.3 Standing for long periods such as 30 minutes?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11.2.4 Taking care of his or her household responsibilities?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11.2.5 Learning a new task, for example learning to get to a new place?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11.2.6 How much of a problem did your relative have joining in community activities (for example festivities, religious or other activities) in the same way as anyone else can?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11.2.7 How much has your relative been emotionally affected by his or her health problems?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11.2.8 Concentrating on doing something for ten minutes?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11.2.9 Walking long distance such as kilometre or equivalent?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11.2.10 Washing his or her whole body?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11.2.11 Getting dressed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11.2.12 Dealing with people he or she does not know?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11.2.13 Maintaining a friendship?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11.2.14 His or her day-to-day work or school?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11.2.15 Overall in the past 30 days, how many day were these difficulties present?	<input style="width: 40px; height: 20px;" type="text"/>				
11.2.16 In the past 30 days, for how many days was your relative totally unable to carry out their usual activities or work because of any health condition?	<input style="width: 40px; height: 20px;" type="text"/>				
11.2.17 In the past 30 days, not counting the days that your relative was totally unable, for how many days did your relative cut back or reduce their usual activities or work because of any health conditions?	<input style="width: 40px; height: 20px;" type="text"/>				

FEISTY II CRF

Patient Study ID

Form 11: 12 Month Follow-up continued

11.3 EQ-5D

Please select ONE option that best describes your health TODAY

If NOT DONE please select this from the dropdown menu on the FEISTY II database

11.3.1 Mobility:

- You have no problems with walking around
- You have slight problems with walking around
- You have moderate problems with walking around
- You have severe problems with walking around
- You are unable to walk around

11.3.2 Personal Care:

- You have no problems with washing or dressing yourself
- You have slight problems with washing or dressing yourself
- You have moderate problems with washing or dressing yourself
- You have severe problems with washing or dressing yourself
- You are unable to wash or dress yourself

11.3.3 Usual activities:

- You have no problems doing your usual activities
- You have slight problems doing your usual activities
- You have moderate problems doing your usual activities
- You have severe problems doing your usual activities
- You are unable to do your usual activities

11.3.4 Pain/discomfort:

- You have no pain or discomfort
- You have slight pain or discomfort
- You have moderate problems doing your usual activities
- You have severe pain or discomfort
- You have extreme pain or discomfort

11.3.5 Anxiety/depression:

- You are not anxious or depressed
- You are slightly anxious or depressed
- You are moderately anxious or depressed
- You are severely anxious or depressed
- You are extremely anxious or depressed

FEISTY II CRF

Patient Study ID

Form 11: 12 Month Follow-up continued

11.4 EQ-VAS

I would now like you to indicate how good or bad your health state is today on a scale of 0-100, with 0 being the 'worst imaginable health state' and 100 being the 'best imaginable health state'.

11.4.1 Health state today / 100

Not done

Best imaginable health state



Worst imaginable health state

<h1 style="margin: 0;">FEISTY II CRF</h1> <h2 style="margin: 0;">Form 11: 12 Month Follow-up continued</h2>	Patient Study ID <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/>
<h3>11.5 Glasgow Outcome Scale – Extended</h3>	
<p>The questions can be answered by the patient or close relative, friend or by rehabilitation / nursing staff if appropriate</p>	
11.5.1 Respondent	<input type="checkbox"/> Patient alone <input type="checkbox"/> Relative or friend or carer alone <input type="checkbox"/> Patient and relative, friend or carer together <input type="checkbox"/> Patient lost to follow-up
<p>If PATIENT LOST TO FOLLOW-UP, END FORM HERE</p>	
<p>Please answer by crossing one box, which best answers the question.</p>	
11.5.2 The injured person is	<input type="checkbox"/> Out of hospital <input type="checkbox"/> In hospital, rehabilitation centre or residential care
11.5.3 What is the most important factor in recovery?	<input type="checkbox"/> Effects of head injury <input type="checkbox"/> Effects of illness or injury to another part of the body <input type="checkbox"/> A mixture of these
11.5.4 Is the injured person able to obey simple commands, or say any words?	<input type="checkbox"/> Yes <input type="checkbox"/> No
11.5.5 Before the injury was injured person able to look after themselves at home?	<input type="checkbox"/> Yes <input type="checkbox"/> No
11.5.6 As a result of the injury does the injured person now need someone to help look after them at home? For a no answer they should be able to look after themselves at home (safely) for 24-hours if necessary. They should not require prompting or reminding and should be capable of being left alone overnight. Cross one of the answers below only.	<input type="checkbox"/> Do not need frequent help or supervision in the home <input type="checkbox"/> Need some help in the home, but can look after themselves for at least 8 hours if necessary <input type="checkbox"/> Could not look after themselves for 8 hours during the day <input type="checkbox"/> Need help in the home but not because of the injury
11.5.7 Before the injury was the injured person able to buy things at shops without help?	<input type="checkbox"/> Yes <input type="checkbox"/> No
11.5.8 As a result of the injury does the injured person now need help to buy things at shops? Cross one of the answers below only.	<input type="checkbox"/> Do not need help to shop (can plan what to buy, take care of money themselves, behave appropriately in public) <input type="checkbox"/> Need help to get to the shops but once there can do own shopping <input type="checkbox"/> Need help to shop <input type="checkbox"/> Need help to shop, but not because of the injury
Form continued on next page	

<h1 style="margin: 0;">FEISTY II CRF</h1> <h2 style="margin: 0;">Form 11: 12 Month Follow-up continued</h2>	Patient Study ID <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/>
<p>11.5 Glasgow Outcome Scale – Extended continued</p> <p>Please answer by crossing one box, which best answers the question.</p>	
<p>11.5.9 Before the injury was the injured person able to travel without help? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<p>11.5.10 As a result of the injury does the injured person now need help to travel? Cross one of the answers below only.</p> <p style="text-align: right;"> <input type="checkbox"/> Do not need help to travel <input type="checkbox"/> Need help to travel <input type="checkbox"/> Need help to travel, but not because of the injury </p>	
<p>11.5.11 Employment before the injury?</p> <p style="text-align: right;"> <input type="checkbox"/> Working <input type="checkbox"/> Studying as a student <input type="checkbox"/> Looking for work <input type="checkbox"/> Retired <input type="checkbox"/> Looking after family <input type="checkbox"/> None of these </p>	
<p>11.5.12 As a result of the injury has there been a change in the injured persons' ability to work? (or study; or to look after your family). Cross one of the answers below only.</p> <p style="text-align: right;"> <input type="checkbox"/> Still do the same work <input type="checkbox"/> Still work, but at a reduced level (e.g. change from FT to PT or change in level of responsibility) <input type="checkbox"/> Am unable to work, or only able to work in a sheltered workshop <input type="checkbox"/> Ability to work has changed, but not because of the injury </p>	
<p>11.5.13 Before the injury did the injured person take part in social and leisure activities outside the home? At least once per week. Examples: going out with or visiting friends, going to the cinema or live performances, attending sporting events or participating in sporting events, attending religious ceremonies or services.</p> <p style="text-align: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<p>11.5.14 As a result of the injury has there been a change in the ability of the injured person to take part in social or leisure activities outside the home? Cross one of the answers below only.</p> <p style="text-align: right;"> <input type="checkbox"/> Take part about as often as before <input type="checkbox"/> Take part a bit less but at least half as often <input type="checkbox"/> Take part much less, less than half as often <input type="checkbox"/> Do not take part at all <input type="checkbox"/> Ability to take part has changed but not because of the injury </p>	
<p>11.5.15 Before the injury did the injured person have any problems getting on with friends?</p> <p style="text-align: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
Form continued on next page	

FEISTY II CRF

Patient Study ID

Form 11: 12 Month Follow-up continued

11.5 Glasgow Outcome Scale – Extended continued

11.5.16 As a result of the injury does the injured person have any emotional or behavioural problems which cause difficulties in relationships with friends or family?

Examples include quick temper, irritability, mood swings, depression, anxiety, insensitivity to others, rigid thinking, unreasonable, childish behaviour

Cross one of the answers below only.

- Things are still much the same
- There are occasional problems (less than once per week)
- There are frequent problems (once a week or more)
- There are constant problems (problems everyday)
- There are problems for some other reason, not because of the injury

11.5.17 Are there currently any other problems resulting from the injury?

Problems sometimes reported after head injury include headaches, dizziness or balance problems, tiredness or sleeping disturbances, sensitivity to noise or light, slower speed of thinking, trouble with memory, concentration problems

Cross one of the answers below only.

- No current problems
- Some problems
- Some problems for other reasons, not because of the head injury

11.5.18 Before the injury were similar problems present?

Cross one of the answers below only.

- No problems or they were minor problems
- Similar problems before

Comments

FEISTY II CRF

Patient Study ID -

Form 12: Adverse Events

12.1 Date of adverse event

- -
d d m m y y y y

12.2 Type of adverse event (select one only)

- Deep Vein Thrombosis
If DVT, complete 12.2.1 Location
- Pulmonary Embolism
- Myocardial Infarction
- Ischaemic Stroke
- Arterial Thromboembolism
- Transfusion reaction
- Other (reportable) adverse event
If OTHER, complete 12.2.2 Details

If Deep Vein Thrombosis

12.2.1 Location

- Upper limb Lower limb Proximal

If Other (reportable) adverse event

12.2.2 Specify details

FEISTY II CRF

Form 13: SAE/SUSAR

Patient Study ID -

Contact Details for SAE Notification (within 24-hours)	
Attention Project Manager	Bridget Ady
Telephone	(03)9905 6643
Email	sae@feisty.org.au

- 13.1 Report type Initial report
 Follow-up report
 Final report
- 13.2 Onset date and time

13.3 Diagnosis

- 13.4 Type Death
 Life threatening
 Prolongation of hospitalisation or rehospitalisation
 Permanently disabling
 Congenital abnormality
 Medically important

13.5 SAE/SUSAR Description (including any treatment):

- 13.6 Last dose of study treatment prior to SAE was: FC
 Cryo
- 13.7 Date and time of last dose of FC/ Cryo
- 13.8 As a result of the SAE the FC/ Cryo was Permanently discontinued
 Temporarily discontinued
 No action

Form continued on next page

FEISTY II CRF		Patient Study ID <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/>
Form 13: SAE/SUSAR continued		
13.9 Outcome	<input type="checkbox"/> Unknown / lost to follow-up <input type="checkbox"/> Unresolved <input type="checkbox"/> Resolved <input type="checkbox"/> Death	
If RESOLVED		
13.9.1 Resolution date	<input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <small>d d m m y y y y</small>	
13.9.2 Status	<input type="checkbox"/> Resolved with sequelae <input type="checkbox"/> Resolved without sequelae	
If RESOLVED WITH SEQUELAE		
13.9.2.1 Specify	<input style="width: 100%; height: 20px;" type="text"/>	
If DEATH		
13.9.3 Date and time of death	<input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <small>d d m m y y y y</small>	
13.9.4 Autopsy done	<input type="checkbox"/> Yes <input type="checkbox"/> No	
13.9.5 Report status	<input type="checkbox"/> Report pending <input type="checkbox"/> Report attached	
13.9.6 Location of death	<input type="checkbox"/> Pre-hospital <input type="checkbox"/> ED <input type="checkbox"/> ICU <input type="checkbox"/> OT/IR <input type="checkbox"/> Ward <input type="checkbox"/> Rehab centre <input type="checkbox"/> Long term care facility <input type="checkbox"/> Other acute hospital <input type="checkbox"/> Home	
13.11 EVENT INFORMATION TO BE DETERMINED BY THE PRINCIPAL INVESTIGATOR OR DELEGATED INVESTIGATOR		
13.11.1 Suspected relationship of SAE to study	<input type="checkbox"/> Not related <input type="checkbox"/> Unlikely related <input type="checkbox"/> Possibly related <input type="checkbox"/> Probably related <input type="checkbox"/> Definitely related	
13.11.2 Is this event a SUSAR (Suspected Unexpected Adverse Event) as determined by the PI or Investigator after review of the study Investigator Brochure?	<input type="checkbox"/> Yes <input type="checkbox"/> No	

FEISTY II CRF

Patient Study ID -

Form 14: Protocol Deviation

14.1 Date and time of protocol deviation

d d m m m y y y y h h m m

- 14.2 Protocol deviation (select one)
- Ineligible: < 18 years of age
 - Ineligible: Pregnant
 - Ineligible: Fibrinogen level outside of range
 - Ineligible: Known objection to blood products
 - Ineligible: Previous Fibrinogen replacement this admission
 - Ineligible: Pre Trauma centre Fibrinogen replacement
 - Ineligible: Participation in competing study
 - Ineligible: Patient has a known coagulation disorder i.e. Haemophilia
 - Patient discharged prior to completion of protocol procedures
 - Enrolled > 6 hours
 - Incorrect dosing of FC
 - Incorrect dosing of Cryoprecipitate
 - Incorrect study treatment
 - Dosage not given (investigator decision / forgotten / not available)
 - Other

If OTHER specify

14.3 Reason and action taken for protocol deviation

Trial Coordinating Centre notified Yes No

FEISTY II CRF

Patient Study ID -

Form 15: Patient Withdrawal

15.1 Date and time of patient withdrawal .. :
d d m m y y y y h h m m

15.2 Person responsible for patient withdrawal Patient or legally authorised representative
 Investigator withdrawal for medical reason
 Other

15.3 Can data be used? Yes No

15.4 Can Day 90, Day 180 & 12 month status be collected? Yes No

15.5 Extra comments / description