# STAMPEDE Key Variables Checklist for Sites

This is a checklist whereby all Case Report Forms (CRFs) received by the STAMPEDE team are checked against upon receipt.
There are general checks which apply to all received CRFs, as well as CRF-specific checks. If any of these checks are not met then queries will be raised with the site asking for further clarification.

| Check | Yes | No | During COVID-19 |
|---|---|---|---|
| Does the **CRF** contain all pages i.e. **no missing pages**?<br>N.B. Blood Form and Death Form – only page 1 is needed | Proceed to CRF-specific checks | Pass form to responsible DM | Pass form onto responsible DM. DM will then raise a query on MACRO, enter onto individual tracker and keep saved to escalate at a later date |
| Is the **CRF** and/or **DCF signed** and **dated**?<br>N.B. This is required on each row of Treatment Logs | | | |
| Have all **patient identifiers** been completed on **CRF**? | | | |

**Table 1: CRF-Specific Checks 1**

| Form | Field | Check the form: |
|---|---|---|
| **Randomisation** *(all)* | Randomisation date is on or after 30-**Nov-2020** | Is version 18<br>Is signed and dated by an authorised person and a clinician |
| | Randomisation date is between **26-NOV-2018** & **29-Nov-2020** | Is version 17<br>Is signed and dated by an authorised person **and** a clinician |
| | Randomisation date is between **05-JAN-2018** & **25-NOV-2018** | Is version 16 |
| | Randomisation date is between **20-JUN-2017** & **04-JAN-2018** | Is version 15 |
| | Randomisation date is between **05-SEP-2016** & **19-JUN-2017** | Is version 14 |
| **Randomisation** *(v17 and further)* | Q2: Eligibility criteria | Has the 'Yes' box ticked<br>The clinician's name and date match the Eligibility Checklist |
| **Randomisation** *(v18 and further)* | Q70 & Q71 | Q70 is answered "2=Abiraterone, 3=Enzalutamide, 4 = Apalutamide" and Q71 answered "L" |
| **Randomisation** *(v17) )* | Q46 & Q47 | Q46 is answered "2=Abiraterone" and Q47 answered "L" |
| **Randomisation** *(v14 – v16)* | Q2: Eligibility criteria | Has the 'Yes' box ticked |
| **Randomisation** *(v13 and prior)* | Q2: Inclusion criteria | Has all 'Yes' boxes ticked |
| | Q3: Exclusion criteria | Has all 'No' boxes ticked |
| | | |
| **Baseline** *(all)* | Randomisation date is between **26-NOV-2018 and 29-Nov-2020** | Is version 15 |
| | Randomisation date is between **05-JAN-2018** & **25-NOV-2018** | Is version 14 |
| | Randomisation date is between **20-JUN-2017** & **04-JAN-2018** | Is version 13 |

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|---|---|---|
| | Randomisation date is between **05-SEP-2016** & **19-JUN-2017** | Is version 12 |
| **Baseline** *(v14 and prior)* | Q6-10: Baseline Investigations | Is answered '1 = Done' (Q8 can be answered '0 = not done', if Q8a is answered '1',) |

| | | |
|---|---|---|
| **Cardiovascular Assessment** *(v15)* | Q13: ECG | Has been answered and has not got anything written indicating patient ineligibility |
| **Cardiovascular Assessment** *(v11 – v14)* | Q16-20: History of Cardiovascular Events | Has not got anything written indicating patient ineligibility |
| **Cardiovascular Assessment** *(v10 and prior)* | Q14-18: History of Cardiovascular Events | Is not answered '2 = Yes, and patient is ineligible' |
| **Form** | | **Check the form:** |
| **Follow Up** *(all)** | Assessment date is on or after **30-Nov-2020** | Is version 17 |
| | Assessment date is between**26-NOV-2018 and 29-Nov-2020** | Is version 16 |
| | Assessment date is between **05-JAN-2018** & **31-DEC-2018** | Is version 15 |
| | Assessment date is between **20-JUN-2017** & **04-JAN-2018** | Is version 14 |
| | Assessment date is between **05-SEP-2016** & **19-JUN-2017** | Is version 13 |
| | Assessment date is **before 05-SEP-2016** | Is version 12 (Follow-Up)<br>Is version 11 (Follow-Up Post Progression) |
| | Weeks 6-24 | Has a lowest PSA provided or if marked not done a reason has been given |
| **Follow up** *(v17)* | Q10: Contraindicated medication | Is completed as '1 = yes', contact CTU' or is left blank, then escalate |
| | Q14c: Emergency/unplanned admission | 'Does the event meet the criteria for a reportable SAE' question is left blank |
| | Q15c: Elective admission | 'Was this admission related to protocol treatment' question is left blank |
| | Q27: Metabolic or cardiac events | Is completed as '1 =yes' or left blank then escalate |
| | | Is completed for **Arm K** patients and Q36 answered as '2 = N/A' |

| | | |
|---|---|---|
| | Q37: Situations occurring whilst on metformin | If Q37 left blank and/or Q37a answered 'no, contact CTU' or left blank then escalate |
| | Q38: Metformin safety monitoring | Is completed for **Arm K** patients and Q36 answered as '2 = N/A' |
| | | If Q38 left blank and/or Q38a answered 'no, contact CTU' or left blank then escalate |
| | Q42: Abiraterone safety monitoring | Is competed for **Arm G and J** patients and Q39 answered as '2 = N/A' |
| | | If Q42 left blank and/or Q42a answered 'no, contact CTU' or left blank then escalate |
| | Q46: Enzalutamide safety monitoring | Is completed for Arm J patients and Q43 answered as '2 = N/A' or Q45 answered '0 = no' |
| | | If Q46 left blank and/or Q46a answered 'no, contact CTU' or left blank then escalate |
| | Q47: Blood pressure | 'Confirm the representative range of blood pressure' is left blank |
| **Follow Up** *(v16)* | Q40: Metformin safety monitoring | Is completed for **Arm K** patients as '1=yes' or '2=not required at this follow-up' and Q40a answered, or Q39 answered '2 = N/A' |
| | | If answered as '0=no, contact CTU' or is left blank then escalate |
| | Q44: Abiraterone safety monitoring | Is completed for **Arm G and J** patients as '1=yes', or Q41 answered '2 = N/A' |
| | | If answered as '0=no, contact CTU' or is left blank then escalate |
| **Follow Up** *(v16 and prior)** | Non-trial visits section | 'Did the event constitute an SAE' question is left blank |
| **Follow Up** *(v15 and prior)** | Q37: Metformin safety monitoring | Is completed for **Arm K** patients as '1=yes' or '2=not required at this follow-up' and Q40a answered, or Q36 answered '2 = N/A' |
| | | If answered as '0=no, contact CTU' or is left blank, then escalate |
| | Q41: Abiraterone safety monitoring | Is completed for **Arm G and J** patients as '1=yes', or Q38 answered '2 = N/A' |
| | | If answered as '0=no, contact CTU' or is left blank, then escalate |
| **Toxicity** *(all)* | All toxicities | If Grade 4 or 5 reported for any toxicity |
| | Q17: Nervous System | If a **seizure** is reported for an **Arm J** Patient |
| | Q14: Metabolism and nutrition disorders | If **Grade 3 or 4 hypokalaemia** is reported for an **Arm G or J** patient |
| | Q13: Investigations | If **Grade 4 increases in AST, ALT or bilirubin** is reported for an **Arm G or J** patient |

**Table 2: CRF-Specific Checks**

| Form | Field | Check the form is not: |
|---|---|---|
| **Treatment Log: Abi' & Enza' or Metformin**<br><br>*(all)* | Dose Column | Answered '99 = other'<br><br>(do not escalate if 'other' dose recorded as an option from the list) |
| **End of Research Treatment**<br><br>*(Arm K only)* | Q3: Reason for stopping treatment | Answered '4 = Disease progression' |
| **Co-enrolment form**<br><br>*(v14)* | Q9 : Confirmation of documented approval for participation in non-prostate cancer trial | If answered as '0 = no, contact CTU' or is left blank for non-prostate cancer trial, then escalate |
| **Additional Treatment Log**<br><br>*(Arm L only)* | Treatment Code Column | Answered "ABI" or "ENZA" or "APA" |
| **Hormone Results Log** | Q1: Standard-of-care(SOC) Abiraterone/Enzalutamide/Apalutamide section | Completed |

| | | |
|---|---|---|
| *(Transdermal Oestradiol, Arm L)* | Results Column: Testosterone | Answered with value >1.7 nmol<br><br>(do not escalate if repeat testosterone performed within 4 weeks is below 1.7 nmol/L) |
| | | Answered as not done |
| | Results Column: Oestradiol | Answered with value <300 or >2000 pmol/L<br><br>(do not escalate if repeat oestradiol performed within 4 weeks is between 300-2000pmol/L) |
| | | Answered as not done |
| **SOC Systemic Therapy form**<br><br>*(Arm L only)* | Q2: Was standard-of-care abiraterone given? **AND** SOC ABIRATERONE Received section.<br><br>Q3: Was standard-of-care enzalutamide given?<br><br>Q4: Was standard-of-care apalutamide given? | Answered '1 = Yes complete SOC ABIRATERONE section<br><br>Answered '1 = Yes complete SOC ENZALUTAMIDE section<br><br>Answered '1 = Yes complete SOC APALUTAMIDE Section |
| | Treatment action Column | Answered '2 = dose change' |

| | | |
|---|---|---|
| **Treatment Log: Transdermal Oestradiol**<br><br>*(all)* | | (do not escalate for the first change from induction to maintenance dose (i.e. 4 to 3 patches), unless testosterone prior change is above 1.7 nmol/L) |
| | Dose Column | Answered '99 = other'<br><br>(do not escalate if 'other' dose recorded as a listed option) |
| | Type Column | Answered '2 = other' |
| **Death Form**<br><br>*(version 12 and below)* | Arms L Q2 – 5 Cause of death | Answered 3, 4, 5, 6 or if cardiovascular is specified in '99 = other'. |
| | Q8 Death related to research treatment | Answered 1, 2 or 3, with Q9 as '2 = No' |
| **Death Form**<br><br>*(version 13 onwards)* | Arms A1, K or L Q2 – 5 Cause of Death | Answered 16 or if cardiovascular is specified in '99 = other' |
| | Q6, 8 & 9: Death related to protocol treatments | Answered as Q6 = 2 **or** Q8 = 1, with Q9 answered as '0 = No' or 1 = "yes" or blank. |