|  |  |  |  |
| --- | --- | --- | --- |
| Patient: |  | Date: |  |
|  | (Study or VMACS ID #) |  | (DDMMMYY) |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Event1** | **Grade** | **AE Start** (DDMMMYY)  | **Attribution2**1=Unrelated, 2= Unlikely, 3=Possible, 4=Probable, 5=Definite | **AE Stop** (DDMMMYY) | **Outcome of AE** |
|  | [ ]  1[ ]  2[ ]  3[ ]  4[ ]  5 | ***or***[ ]  Started prior to study | Research3 |  | ***or***[ ]  Still present at end of study | [ ]  Recovered[ ]  Recovered with sequelae6[ ]  Death[ ]  Unknown |
| IVP4 |  |
| Disease5 |  |
| Unknown/other: |  |
|  |
|  | [ ]  1[ ]  2[ ]  3[ ]  4[ ]  5 | ***or***[ ]  Started prior to study | Research3 |  | ***or***[ ]  Still present at end of study | [ ]  Recovered[ ]  Recovered with sequelae6[ ]  Death[ ]  Unknown |
| IVP4 |  |
| Disease5 |  |
| Unknown/other: |  |
|  |  |
|  | [ ]  1[ ]  2[ ]  3[ ]  4[ ]  5 | ***or***[ ]  Started prior to study | Research3 |  | ***or***[ ]  Still present at end of study | [ ]  Recovered[ ]  Recovered with sequelae6[ ]  Death[ ]  Unknown |
| IVP4 |  |
| Disease5 |  |
| Unknown/other: |  |
|  |  |
|  | [ ]  1[ ]  2[ ]  3[ ]  4[ ]  5 | ***or***[ ]  Started prior to study | Research3 |  | ***or***[ ]  Still present at end of study | [ ]  Recovered[ ]  Recovered with sequelae6[ ]  Death[ ]  Unknown |
| IVP4 |  |
| Disease5 |  |
| Unknown/other: |  |
|  |  |
|  | [ ]  1[ ]  2[ ]  3[ ]  4[ ]  5 | ***or***[ ]  Started prior to study | Research3 |  | ***or***[ ]  Still present at end of study | [ ]  Recovered[ ]  Recovered with sequelae6[ ]  Death[ ]  Unknown |
| IVP4 |  |
| Disease5 |  |
| Unknown/other: |  |
|  |  |

1. Use VCOG-CTCAE term (VCOG-CTCAE v2, 2021) to describe the Adverse Event where possible. For Adverse Events not defined by VCOG-CTCAE v2, assign severity grades as follows: 1 (mild), 2 (moderate), 3 (severe), 4 (life-threatening), 5 (death).
2. For each category, record a number to indicate the likelihood that the AE is attributable to Research, IVP, Disease, or Other/Unknown (explain briefly in space below)
3. Examples of AEs attributable to “research” may be anemia after serial blood collection, stress colitis due to hospitalization for research procedures, unexpected anesthetic event, etc.
4. IVP, Investigational Veterinary Product
5. For condition/disease diagnosed pre-enrollment; if the severity is higher than at enrollment, then do not check this box for causality.
6. Mark “Recovered with sequelae” if AE has not resolved but rather increased to a higher grade