#define X-VAULT-EMPTYVALUE “N/A”

| **Interim Monitoring Visit Report** | | |
| --- | --- | --- |
| Protocol No: | ${study\_\_ctmsr.name\_\_v} | |
| Study Title: | ${study\_\_ctmsr.protocol\_title\_\_clin} | |
| Site / PI: | ${site\_\_ctmsr.name\_\_v} | ${site\_\_ctmsr.principal\_investigator\_\_v} |
| CRA: | ${study\_person\_\_ctmsr.name\_\_v} | |
| Visit Date(s): | ${actual\_visit\_start\_date\_\_ctms} - ${actual\_visit\_end\_date\_\_ctms} | |

| ${Rowset(monitoring\_visit\_participants\_\_ctmsr WHERE attended\_\_ctms = true)}  ${HideTableIf(Rowsetcount()=0)}  **Visit Attendees** | |
| --- | --- |
| **Name** | **Role** |
| ${RepeatRow()}  ${name\_\_v} | ${role\_\_v} |

| ${Rowset(site\_\_ctmsr)}  **Primary Site Location** |
| --- |
| |  | | --- | | ${Rowset(location\_\_vr)}  ${name\_\_v}  ${location\_type\_\_v}  ${address\_line\_1\_\_clin}  ${address\_line\_2\_\_clin}  ${town\_city\_\_clin}, ${state\_province\_region\_\_clin} ${postal\_zip\_code\_\_clin}  ${country\_\_v} | |

|  |  |
| --- | --- |
| ${Rowset(monitored\_study\_site\_addresses\_\_vr)}  ${HideTableIf(Rowsetcount()=0)}  **Monitored Study Site Addresses** | |
| **Site Address** | **Country** |
| ${RepeatRow()}  ${site\_address\_\_v} | ${country\_\_v} |

|  |  |
| --- | --- |
| ${Rowset(monitored\_metrics\_\_ctmsr)}  ${HideTableIf(Rowsetcount()=0)}  **Monitored Metrics** | |
| **Metric** | **Actual** |
| ${RepeatRow()}  ${metric\_type\_\_ctms} | ${actual\_\_ctms} |

| ${Rowset(question\_responses\_\_ctmsr WHERE trip\_report\_section\_type\_\_ctms = 'imv\_section\_1\_\_c' ORDER BY order\_\_ctms)}  **IMV Section 1** | | | |
| --- | --- | --- | --- |
| **Order** | **Question** | **Response** | **Comments** |
| ${RepeatRow()}  ${order\_\_ctms} | ${question\_text\_\_ctms} | |  | | --- | | ${HideRowIf(IsBlank(long\_response\_text\_\_v))}  ${long\_response\_text\_\_v} | | |  | | --- | | ${Rowset(trip\_report\_answers\_\_ctmsr)}  ${RepeatRow()}  ${HideRowIf(IsBlank(answer\_\_ctms))}  ${answer\_\_ctms} | | | ${long\_comment\_\_v} |

| ${Rowset(question\_responses\_\_ctmsr WHERE trip\_report\_section\_type\_\_ctms = 'imv\_section\_2\_\_c' ORDER BY order\_\_ctms)}  **IMV Section 2** | | | |
| --- | --- | --- | --- |
| **Order** | **Question** | **Response** | **Comments** |
| ${RepeatRow()}  ${order\_\_ctms} | ${question\_text\_\_ctms} | |  | | --- | | ${HideRowIf(IsBlank(long\_response\_text\_\_v))}  ${long\_response\_text\_\_v} | | |  | | --- | | ${Rowset(trip\_report\_answers\_\_ctmsr)}  ${RepeatRow()}  ${HideRowIf(IsBlank(answer\_\_ctms))}  ${answer\_\_ctms} | | | ${long\_comment\_\_v} |

| ${Rowset(question\_responses\_\_ctmsr WHERE trip\_report\_section\_type\_\_ctms = 'imv\_section\_3\_\_c' ORDER BY order\_\_ctms)}  **IMV Section 3** | | | |
| --- | --- | --- | --- |
| **Order** | **Question** | **Response** | **Comments** |
| ${RepeatRow()}  ${order\_\_ctms} | ${question\_text\_\_ctms} | |  | | --- | | ${HideRowIf(IsBlank(long\_response\_text\_\_v))}  ${long\_response\_text\_\_v} | | |  | | --- | | ${Rowset(trip\_report\_answers\_\_ctmsr)}  ${RepeatRow()}  ${HideRowIf(IsBlank(answer\_\_ctms))}  ${answer\_\_ctms} | | | ${long\_comment\_\_v} |

| ${Rowset(monitored\_subjects\_\_ctmsr)}  ${HideTableIf(Rowsetcount()=0)}  **Subjects** | | | | |
| --- | --- | --- | --- | --- |
| **Monitored Subject ID** | **Subject status** | **Screened Date** | **Screen Failed Date** |  |
| ${RepeatRow()}  ${name\_\_v} | ${subject\_status\_\_ctms} | ${screened\_date\_\_v} | ${screen\_failed\_date\_\_v} |  |

| ${Rowset(monitored\_subject\_visits\_\_vr)}  ${HideTableIf(Rowsetcount()=0)}  **Subject Visit SDV** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Subject** | **Visit** | **Visit Date** | **Visit Status** | **Visit Method** | **SDV Complete?** |
| ${RepeatRow()}  ${monitored\_subject\_\_v} | ${visit\_def\_\_v} | ${visit\_date\_\_v} | ${visit\_status\_\_v} | ${visit\_method\_\_v} | ${rev\_sdv\_\_v} |

| ${Rowset(monitored\_sdr\_items\_\_vr)}  ${HideTableIf(Rowsetcount()=0)}  **Subject Visit SDR** | | | |
| --- | --- | --- | --- |
| **Subject** | **Subject Visit** | **SDR Complete?** |
| ${RepeatRow()}  ${monitored\_subject\_\_v} | ${subject\_visit\_\_v} | ${sdr\_complete\_\_v} |

| ${Rowset(monitored\_icfs\_\_ctmsr)}  ${HideTableIf(Rowsetcount()=0)}  **Monitored Informed Consent Forms** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Monitored ICF ID** | **Subject** | **ICF** | **Signature Date** | **ICF Document** | **Site Effective Date** |
| ${RepeatRow()}  ${name\_\_v} | ${monitored\_subject\_\_ctms} | ${master\_informed\_consent\_name\_\_c} | ${informed\_consent\_signature\_date\_\_ctms} | ${master\_informed\_consent\_name\_\_c} | ${site\_effective\_date\_\_ctms} |

| ${Rowset(pdv\_logs\_\_ctmsr)}  ${HideTableIf(Rowsetcount()=0)}  **New Issues** | | | |
| --- | --- | --- | --- |
| **Number** | **Type** | **Subject** | **Summary** |
| ${RepeatRow()}  ${name\_\_v} | ${object\_type\_\_v} | ${subject\_\_ctms} | ${summary\_\_ctms} |

| ${Rowset(monitored\_protocol\_deviations\_\_vr WHERE issue\_\_vr.resolved\_date\_\_v = null)}  ${HideTableIf(Rowsetcount()=0)}  **Open Issues** | | | |
| --- | --- | --- | --- |
| **Number** | **Type** | **Subject** | **Summary** |
| ${RepeatRow()}  ${issue\_\_vr.name\_\_v} | ${issue\_\_vr.object\_type\_\_v} | ${issue\_\_vr.subject\_\_ctms} | ${issue\_\_vr.summary\_\_ctms} |

| ${Rowset(monitored\_protocol\_deviations\_\_vr WHERE issue\_\_vr.resolved\_date\_\_v != null)}  ${HideTableIf(Rowsetcount()=0)}  **Closed Issues Since Last Visit** | | | |
| --- | --- | --- | --- |
| **Number** | **Type** | **Subject** | **Summary** |
| ${RepeatRow()}  ${issue\_\_vr.name\_\_v} | ${issue\_\_vr.object\_type\_\_v} | ${issue\_\_vr.subject\_\_ctms} | ${issue\_\_vr.summary\_\_ctms} |

| ${Rowset(monitored\_opened\_before\_current\_\_vr WHERE monitoring\_follow\_up\_item\_\_vr.completion\_date\_\_v = null)}  ${HideTableIf(Rowsetcount()=0)}  **Open Follow Up Items** | | | |
| --- | --- | --- | --- |
| **Task Name** | **Opened Date** | **Due Date** | **Description** |
| ${RepeatRow()}  ${monitoring\_follow\_up\_item\_\_vr.name\_\_v} | ${monitoring\_follow\_up\_item\_\_vr.opened\_date\_\_clin} | ${monitoring\_follow\_up\_item\_\_vr.due\_date\_\_v} | ${monitoring\_follow\_up\_item\_\_vr.description\_\_v} |

| ${Rowset(monitored\_closed\_since\_last\_\_vr WHERE monitoring\_follow\_up\_item\_\_vr.completion\_date\_\_v != null)}  ${HideTableIf(Rowsetcount()=0)}  **Closed Follow Up Items Since Last Visit** | | | | |
| --- | --- | --- | --- | --- |
| **Task Name** | **Opened Date** | **Due Date** | **Closed Date** | **Description** |
| ${RepeatRow()}  ${monitoring\_follow\_up\_item\_\_vr.name\_\_v} | ${monitoring\_follow\_up\_item\_\_vr.opened\_date\_\_clin} | ${monitoring\_follow\_up\_item\_\_vr.due\_date\_\_v} | ${monitoring\_follow\_up\_item\_\_vr.completion\_date\_\_v} | ${monitoring\_follow\_up\_item\_\_vr.description\_\_v} |

| ${Rowset(esig\_\_sysr)}  **Signatures** | | | | |
| --- | --- | --- | --- | --- |
| **Signature ID** | **Signatory** | **Capacity** | **Verdict** | **Signature DateTime** |
| ${RepeatRow()}  ${name\_\_v} | ${signature\_name\_\_sys} | ${signature\_meaning\_\_sys} | ${verdict\_\_sys} | ${signature\_time\_\_sys} |