| **PTID:**  | **Call****Date:** |
| --- | --- |
| **\_\_\_\_ Call following Visit 16** | **\_\_\_\_ Call following Visit 32 (Visit Code 33.0)****Note: Visit 33.0 is considered Study Termination Visit** |
|  |  |
| **Initials** | **Procedures** |
|  | 1. Confirm participant identity and PTID per site SOPs |
|  | 2. Review/Update locator information |
|  | 3. Collect AEs if indicated and document on AE Log form |
|  | 4. If indicated, schedule interim visit for follow-up of identified AEs |
|  | 5. Provide instructions to report symptoms and/or request information or counseling. |
|  | 6. Provide reimbursement per site SOP. |
|  | 7. Remind participant of next visit, if applicable.  |
|  | 8. If applicable, fax all completed DataFax forms to SCHARP DataFax:* Visit Summary (if new AE(s) or Product Holds are reported/initiated)
* Adverse Experience Log
* Clinical Product Hold/Discontinuation Log
* Concomitant Medications Log

**At Visit 33.0 (Study Termination Visit),** complete and fax the following forms to SCHARP DataFax:* Follow-up Visit Summary
* End of Study Inventory
* Termination

If applicable at Visit 33.0, fax all completed DataFax forms to SCHARP DataFax:* Adverse Experience Log
* Update Clinical Product Hold/Discontinuation Log
* Concomitant Medications
* Missed Visit
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