



Patient Initials [ ][ ][ ]

PB-SAM Number [1][0] [ ][ ][ ]

| Day 21 Follow Up |  |   |
|------------------|--|---|
| 1. VISIT DETAILS |  |   |
| 1.1.             | Date seen or contacted on phone                | ___/___/_____<br>D D / M M / Y Y Y Y  |
| 1.2.             | Time seen or contacted on phone<br>(24H Clock) | ___:___<br>(24H Clock)  |
| 1.3.             | Seen at  | <input type="checkbox"/> Hospital / clinic <input type="checkbox"/> Hospital inpatient <input type="checkbox"/> In Community<br><br><input type="checkbox"/> Confirmed vital status phone - alive<br><br><input type="checkbox"/> Confirmed vital status phone – dead |

| 2. ANTHROPOMETRY |  |   |
|------------------|--|---|
| 2.1.             | Weight<br>(to be taken using SECA scales for CHAIN study)  | ___ . ___ kg  |
| 2.2.             | Length/ height<br>(Select ONE)<br>(Length measured lying down if participant less than 24 months and height measured standing) | <input type="checkbox"/> Length <input type="checkbox"/> Height<br>(to be taken using SECA 416 infantometer provided for study)<br><br>Measurer 1: ___ . ___ cm      Measurer 2: ___ . ___ cm |
| 2.3.             | MUAC<br>(To be taken using MUAC tape for CHAIN study)  | Measurer 1: ___ . ___ cm      Measurer 2: ___ . ___ cm  |
| 2.4.             | Head circumference<br>(To be taken using CHAIN measuring tape)   | Measurer 1: ___ . ___ cm      Measurer 2: ___ . ___ cm  |
| 2.5.             | Oedema<br>(Select ALL that apply)  | <input type="checkbox"/> None <input type="checkbox"/> both feet/ankles <input type="checkbox"/> lower legs<br><input type="checkbox"/> hands or lower arms <input type="checkbox"/> face     |
| 2.6.             | Growth changes consistent with previous measurements?  | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not available<br>(If no, consider to be wrong measurement, child or file)                                   |
| 2.7.             | Staff Initials   | Measurer 1: _____      Measurer 2: _____  |



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| 3. HOSPITAL ADMISSIONS |   |  |
|------------------------|---|--|
| <b>3.1.</b>            | <b>Any admissions (e.g. overnight stay) to a hospital since discharge? (i.e. Readmission)</b> | <input type="checkbox"/> Yes <span style="float: right;"><input type="checkbox"/> No</span><br><i>If YES (Complete SAE form)</i>   |
|                        | <b>If Yes</b>   |  |
|                        | a) <b>Re-admission date 1:</b><br><i>(If not known estimate)</i>                              | ____/____/_____<br><i>D D / M M / Y Y Y Y</i><br><br><input type="checkbox"/> Definite date <span style="margin-left: 100px;"><input type="checkbox"/> Estimated date</span> |
|                        | b) <b>Date of discharge 1</b>   | ____/____/_____<br><i>D D / M M / Y Y Y Y</i><br><br><input type="checkbox"/> Definite date <span style="margin-left: 100px;"><input type="checkbox"/> Estimated date</span> |
|                        | c) <b>Source of information 1</b><br><i>(Select ALL that apply)</i>                           | <input type="checkbox"/> Hospital letter or medical file <span style="margin-left: 100px;"><input type="checkbox"/> Parent/carer report</span>                               |
| <b>3.2.</b>            | <b>If Second admission</b>  | <input type="checkbox"/> <b>Not applicable</b>   |
|                        | a) <b>Re-admission date 2</b><br><i>(If not known, estimate)</i>                              | ____/____/_____<br><i>D D / M M / Y Y Y Y</i><br><br><input type="checkbox"/> Definite date <span style="margin-left: 100px;"><input type="checkbox"/> Estimated date</span> |
|                        | b) <b>Date of discharge 2</b>   | ____/____/_____<br><i>D D / M M / Y Y Y Y</i><br><br><input type="checkbox"/> Definite date <span style="margin-left: 100px;"><input type="checkbox"/> Estimated date</span> |
|                        | c) <b>Source of information 2</b><br><i>(Select ALL that apply)</i>                           | <input type="checkbox"/> Hospital letter or medical file <span style="margin-left: 100px;"><input type="checkbox"/> Parent/carer report</span>                               |
| <b>3.3.</b>            | <b>If third admission</b>   | <input type="checkbox"/> <b>Not applicable</b>   |
|                        | a) <b>Re-admission date 3</b><br><i>(If not known, estimate)</i>                              | ____/____/_____<br><i>D D / M M / Y Y Y Y</i><br><br><input type="checkbox"/> Definite date <span style="margin-left: 100px;"><input type="checkbox"/> Estimated date</span> |
|                        | b) <b>Date of discharge 3</b>   | ____/____/_____<br><i>D D / M M / Y Y Y Y</i><br><br><input type="checkbox"/> Definite date <span style="margin-left: 100px;"><input type="checkbox"/> Estimated date</span> |
|                        | c) <b>Source of information 3</b><br><i>(Select ALL that apply)</i>                           | <input type="checkbox"/> Hospital letter or medical file <span style="margin-left: 100px;"><input type="checkbox"/> Parent/carer report</span>                               |



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| CURRENT HEALTH |  |
|----------------|--|
| 3.4.           | <p><b>What symptoms were noticed in the last 7 days?</b><br/> <i>If any meet criteria for Grade 3 or 4 toxicity, then a toxicity CRF must also be filled. Refer to SAE and Toxicity SOP.</i><br/> <b>(Select ALL that apply)</b></p> |

- No symptoms, child is well
- Fever
- Vomiting
- Diarrhoea
- Blood in stool
- Cough
- Difficulties with feeding/loss of appetite
- Difficulty breathing
- Yellowness of skin/eyes
- Rash / skin lesion

| MEDICATIONS AT DAY 21 |  |
|-----------------------|--|
| 3.5.                  | <p><b>Enzyme/Placebo:</b></p> <p>a) Bottle 1</p> <p style="padding-left: 20px;">i). Weight _____ . _____ grams</p> <p style="padding-left: 20px;">ii). Usage <input type="checkbox"/> Used completely   <input type="checkbox"/> Partly Used   <input type="checkbox"/> Returned as unused   <input type="checkbox"/> Not Returned</p> |
|                       | <p>b) Bottle 2</p> <p style="padding-left: 20px;">i). Weight _____ . _____ grams</p> <p style="padding-left: 20px;">ii). Usage <input type="checkbox"/> Used completely   <input type="checkbox"/> Partly Used   <input type="checkbox"/> Returned as unused   <input type="checkbox"/> Not Returned</p>                               |
| 3.6.                  | <p><b>Urso/Placebo:</b></p> <p>c) Bottle 1</p> <p style="padding-left: 20px;">i). Weight _____ . _____ grams</p> <p style="padding-left: 20px;">ii). Usage <input type="checkbox"/> Used completely   <input type="checkbox"/> Partly Used   <input type="checkbox"/> Returned as unused   <input type="checkbox"/> Not Returned</p>   |
|                       | <p>d) Bottle 2</p> <p style="padding-left: 20px;">ii). Weight _____ . _____ grams</p> <p style="padding-left: 20px;">iii). Usage <input type="checkbox"/> Used completely   <input type="checkbox"/> Partly Used   <input type="checkbox"/> Returned as unused   <input type="checkbox"/> Not Returned</p>                             |



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| f) Outpatient Appointments |   |  |
|----------------------------|---|--|
| 3.7.                       | a) <b>Attended Nutrition follow-up since discharge</b><br><i>(Select ONE)</i> | <input type="checkbox"/> Yes <input type="checkbox"/> No |

| g) FEEDING |   |  |
|------------|---|--|
| 3.8.       | <b>Currently in outpatient nutrition program?</b><br><i>Select one. If not in feeding program circle 'none'</i>   | <input type="checkbox"/> None <input type="checkbox"/> Supplementary <input type="checkbox"/> Therapeutic<br><i>(corn soy blend, RUSF, (RUTF, Plumpy-nut)</i><br><i>khichuri, halwa etc)</i> |
| 3.9.       | <b>How many times attended since discharge</b>  | __ __  times   |
| 3.10.      | <b>Has the child eaten the following nutrition products in the last 3 days?</b><br><b>(Select ALL that apply)</b> | <input type="checkbox"/> None <input type="checkbox"/> Supplementary <input type="checkbox"/> Therapeutic  |

| PLAN DAY 60 VISIT |                                 |   |
|-------------------|---------------------------------|---|
| 3.11.             | <b>Date of next visit</b>       | ____/____/_____<br><i>D D/M M/ Y Y Y Y</i>  |
| 3.12.             | <b>Any new contact details?</b> | <input type="checkbox"/> Yes <input type="checkbox"/> No<br><br>If Yes, details _____ |



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**D21 INVESTIGATIONS AND SAMPLE COLLECTIONS**

|       |   |   |
|-------|---|---|
| 3.13. | <b>EDTA blood sample taken</b>  | <input type="checkbox"/> Yes <input type="checkbox"/> No  |
| 3.14. | <b>Date and Time EDTA blood taken</b>   | <p>___/___/_____<br/> <i>D D/M M/ Y Y Y Y</i></p> <p>____:____<br/> <i>(24H Clock)</i></p>  |
| 3.15. | <b>If unable to take blood samples, why?<br/>(Select ONE)</b>                                   | <input type="checkbox"/> Difficult venepuncture<br><input type="checkbox"/> Child uncooperative <input type="checkbox"/> Parent refused<br><input type="checkbox"/> Other venepuncture within 12h |
| 3.16. | <b>a) Rectal swabs taken</b>  | <input type="checkbox"/> Yes <input type="checkbox"/> No  |
|       | <b>b) Date and Time Rectal swabs taken</b>  | <p>___/___/_____<br/> <i>D D/M M/ Y Y Y Y</i></p> <p>____:____<br/> <i>(24H Clock)</i></p>  |
| 3.17. | <b>Stool sample taken</b>   | <input type="checkbox"/> Yes <input type="checkbox"/> No  |
| 3.18. | <b>Date and Time Stool taken</b>  | <p>___/___/_____<br/> <i>D D/M M/ Y Y Y Y</i></p> <p>____:____<br/> <i>(24H Clock)</i></p>  |
| 3.19. | <b>Blood Samples taken by (initials)</b><br>(Select N/A if blood sample was not collected)      | <input type="checkbox"/> N/A _____  |
| 3.20. | <b>Rectal Swabs taken by (initials)</b><br>(Select N/A if rectal swab sample was not collected) | <input type="checkbox"/> N/A _____  |
| 3.21. | <b>Stool taken by (initials)</b><br>(Select N/A if stool sample was not collected)              | <input type="checkbox"/> N/A _____  |



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| CRF COMPLETION |  |  |
|----------------|--|--|
| 3.22.          | <b>a) CRF Completed by (Initials) – to be signed when complete</b><br><i>Do not sign if any fields are empty</i> | _____                                  |
|                | <b>b) Date</b>   | ____/____/_____<br>D D / M M / Y Y Y Y |
|                | <b>c) Time</b><br>(24 hr clock)  | ____:____                              |
| 10.2           | <b>d) CRF Reviewed by (Initials)</b>   | _____                                  |
|                | <b>e) Date</b>   | ____/____/_____<br>D D / M M / Y Y Y Y |
|                | <b>f) Time</b><br>(24 hr clock)  | ____:____                              |