SCREENING — STAGE 1

❖ After potential child is identified in nutritional rehabilitation unit or clinic, obtain informed consent for screening from family/guardian, and obtain screening number.

❖ If participant does not enroll for any reason, a screening failure CRF must be entered. Use screening number in form header. CRF collects same reasons as stated within Inclusion/Exclusion section 4.0, plus death and opting out.

❖ Screening numbers expire 30 days after being issued.
SCREENING FAILURE

Screening Failure Form

- Lymphocyte Subsets
- HIV-1 RNA
- Mid-upper Arm Circumference
- World Health Organization Z-Score
- Documentation of HIV Infection
- Inclusion/Exclusion Criteria

Nutrition Assessment
SCREENING/ENROLLMENT — STAGE 2

Cohort 1: Severe Malnutrition

Screening evaluation must be performed within 18 days prior to entry

- For children with severe malnutrition, entry into the study will occur after informed consent for study participation has been obtained and within 10 - 18 days after the day of admission to the nutritional rehabilitation unit. Before these children can advance to Stage 2, they must be judged by the clinician to have improved clinically and be eligible to begin the study HAART regimen.

Cohort 2: Normal Nutrition/Mild Malnutrition

Screening evaluation must be performed within 14 days prior to entry

- For children with normal nutrition/mild nutrition who are found to be eligible, entry into the study will occur after written informed consent has been obtained and within 7 - 14 days after screening. Before these children can advance to Stage 2, they must be judged by their clinician to be clinically stable and eligible to begin the study HAART regimen.
ENROLLMENT

ACTG/IMPAACT Subject Enrollment System

Institution: TEST
Protocol: PS2001
Step 1: IMPAACT Screening Log

Eligibility Checklist:

Q0001
IMPAACT Screening Log
Checklist Date: April 11, 2011
☐ Click here to continue!

Q0009
Enter today’s date at the subject’s assigned site.

dd/mm/yyyy:

Q0010
System will check the number of DAYS from Q0009 to TODAY

- if less than -1, Ineligible
- if less than or equal to 0, next question
- if greater than 0, Ineligible
- if unknown, Ineligible
☐ Click here to continue!

Q0002
Enter the study number for which the subject needs a Screening Number. NOTE: All characters must be entered in upper case.

Frontier Science Enrollment System

Institution:
Protocol: P1092
Version: 2
Step 1:

Blank Eligibility Checklist:

Q0001
Protocol IMPAACT P1092 Version 2.0
Phase IV evaluation of the steady state pharmacokinetics of Iloviride, lamivudine, and Lopinavir/ritonavir in severely malnourished HIV-1-infected children
Eligibility Checklist Date: June 5, 2015
☐ Click here to continue!

Q0002
Has the participant been previously enrolled in other IMPAACT/FACTS STUDIES?

REMINDER: IF THE PARTICIPANT HAS BEEN PREVIOUSLY ENROLLED IN ANY OTHER IMPAACT/FACTS STUDY, BE SURE TO USE THE SAME PID NUMBER FOR ALL STUDIES, INCLUDING THIS STUDY, IMPAACT P1092.

☐ Yes [next question]
☐ No [next question]
☐ Unknown [next question]

Q0003
Enter PID:

Q0004
Enter today’s date at the participant’s assigned site.

dd/mm/yyyy:

PS Screening Number
**TREATMENT RECORD: TXW0267**

**NOTE:** Kaletra is provided as 80 mg Lopinavir/20 mg Ritonavir per 1mL oral solution. For example: If participant weighs 10.5 kg, they should receive 2.0 mL of Kaletra solution and receive 160 mg Lopinavir and 40 mg Ritonavir. If taken BID, record 320 mg Lopinavir and 80mg Ritonavir as Total Daily dose taken.

<table>
<thead>
<tr>
<th>Dose Status</th>
<th>Date Modification Started</th>
<th>LPV Total Daily Dose (mg)</th>
<th>RTV Total Daily Dose (mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 3</td>
<td>15 JUN 2015</td>
<td>320.0</td>
<td>80.0</td>
</tr>
</tbody>
</table>

**Specify Drug [70]:** Kaletra

**Specify Reason for Modification [70]:** Weight change
INTENSIVE PHARMACOKINETICS: PKW0331

1. Were specimens obtained for intensive pharmacokinetics at this visit? (1-Yes, 2-No)
   - If No, complete ‘ta’ and STOP. Do not send form to lab.
   - If Yes, go to question 2.
   a. Reason specimens not obtained: 1-Not eligible for pharmacokinetics. specify __________
      9-Other. specify __________

NOTE: Participants are ineligible for intensive pharmacokinetics if:
- Hemoglobin was <7.5 g/dL at most recent prior evaluation.
- They are severely malnourished and have not nutritionally and/or clinically improved.
- They develop edema.
- They have diarrhea.
- They missed any ARV doses within the prior 72 hours.
Specify reason(s) not obtained [70]:

FOOD INTAKE
6. Was any food, milk or formula consumed within either 2 hours before taking clinic PK dose or within 2 hours after taking PK dose? (1-Yes, 2-No)
   - If No, go to question 7.
   - If Yes, continue.
   Record food intake information.
   Use the Tab Key after the last entry.

<table>
<thead>
<tr>
<th>Food Types</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>10-RTUF</td>
<td>1-ml</td>
</tr>
<tr>
<td>11-F100</td>
<td>2-gm</td>
</tr>
<tr>
<td>12-Milk, specify type (breast, cow, goat, canned)</td>
<td>S-number</td>
</tr>
<tr>
<td>13-Yogurt</td>
<td></td>
</tr>
<tr>
<td>14-Eggs</td>
<td></td>
</tr>
<tr>
<td>15-Enriched porridge, maize (margarine may be added)</td>
<td></td>
</tr>
<tr>
<td>16-Enriched porridge, egg (margarine may be added)</td>
<td></td>
</tr>
<tr>
<td>17-Enriched porridge, mixed grains (margarine may be added)</td>
<td></td>
</tr>
<tr>
<td>18-Enriched porridge, other, specify (margarine may be added)</td>
<td></td>
</tr>
<tr>
<td>19-Infant Formula</td>
<td></td>
</tr>
<tr>
<td>99-Other, specify</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Food Type</th>
<th>Specify [79]:</th>
<th>Quantity Offered</th>
<th>Units</th>
<th>Quantity Consumed</th>
<th>Meal Start Time (h:m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a.</td>
<td>Egg</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>07:15</td>
</tr>
<tr>
<td>b.</td>
<td>Plumpy Nut</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>09:15</td>
</tr>
<tr>
<td>c.</td>
<td>Milk, cow</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>11:00</td>
</tr>
<tr>
<td>d.</td>
<td>Maize porridge with margarine</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>12:55</td>
</tr>
</tbody>
</table>
ANTHROPOMETRIC MEASUREMENTS

For Protocol P1092: MUAC is required at all study visits.

Skin fold thickness (triceps) at Entry, weeks 24 and 48.
### DATA COLLECTION FORMS SCHEDULE

**STUDY P1092**  
**BOOK 1 - VERSION 2.0**

**NOTE:** The columns are marked with either an "X" or "V" to indicate data and evaluations required at each visit.  
X = Required form.  
V = Evaluation required; data may be required.

<table>
<thead>
<tr>
<th>WEEKS</th>
<th>SCREENING</th>
<th>ENTRY</th>
<th>ON STUDY DRUG</th>
<th>OFF STUDY DRUG</th>
<th>Premature Discontinuation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>2</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>ADM0022(P1092)</td>
<td>Initiation Of Study Defined Medication/Regimen - II</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>ADM0040(P1092)</td>
<td>Visit Status Report</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>PE8905(P1092)</td>
<td>Hospitalization Record - III</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

---

**ADM0022 Initiation of Study Defined Medication/Regimen – II:** Submitted at Week 1 visit, not Entry.

Document expected hospitalization for Cohort 1 management of Severe Acute Malnutrition (SAM). For Cohort 2 only document hospitalization if applicable for Mildly Malnourished participants. For all others indicate no hospitalization at Entry.

Chemistries include: AST, ALT, creatinine, sodium, potassium, chloride, and bicarbonate. Obtain glucose in fasting state if participant is clinically stable. For 6-24 months of age: 3-hour fasting; for >24 months of age: 6-hour fasting.

Perform Total Protein and Albumin tests at this visit.

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| PE8818(P1092) | Chemistry - IV | X       | X       | X       | X       | X |
| PE8839(P1092) | Signs and Symptoms - IV | X       | X       | X       | X       | X |
| PE8859(P1092) | Diagnoses - IV | X       | X       | X       | X       | X |
| PE8866(P1092) | Event Evaluation - VI | X       | X       | X       | X       | X |
| FW0331(P1092) | IMPACT P1092 Intensive Pharmacokinetics | X       | X       | X       | X       | X |
| FW0332(P1092) | IMPACT P1092 Trough Pharmacokinetics | X       | X       | X       | X       | X |
| TX0267(P1092) | IMPACT P1092 Study Treatment Record | X       | X       | X       | X       | X |

Footnotes are located on page 2.
Contact Information

If you have questions about schedules or forms, e-mail the Protocol Data Managers:
- Bobbie Graham: graham@fstrf.org
- Amanda Golner: golner@fstrf.org

If you have questions about eData, Smart Update, or other technical issues, email User Support:
- usersprt@fstrf.org

If you have questions about participant management or the protocol itself, email the P1092 Protocol Team:
- impaact.teamp1092@fstrf.org

The Prot email group is used by the Protocol Team to disseminate information to registered sites:
- impaact.protp1092@fstrf.org