INOCULATION DAY 0

Recruitment → Consent → Screening → Inoculation → Study Visit → RSV Seasonal Surveillance
INOCULATION DAY

ACUTE AND POST-ACUTE PHASE

- Screening/blood collection within 42 days of enrollment
- Clinical assessment: inoculation & 8 visits
- Nasal wash
- Acute Phase
- Blood and nasal wash collection
- Post-Acute Phase

Scheduled In-person Visit
- Obtain medical records from PMD to review for eligibility
- Evaluate for
  - Chronic illness
  - Child’s growth
  - Current medications
  - Acute illness
- Questions about potential eligibility, email IMPAACT Protocol Team (impaact.team2013@fstrf.org) including ”IMPAACT 2013” in subject of the message
Subjects must meet all the inclusion criteria.
Subjects must not meet any of the exclusion criteria.
Enroll in IMPAACT 2013 by utilizing the Subject Enrollment System (SES)
- located on the IMPAACT DMC website at www.fstrf.org
2:1 ratio of RSV D46/NS2/N/ΔM2-2-HindIII, Lot RSV #011B vs. placebo.
Goal: Randomize and inoculate on the same day
- Site has up to 72 hours after randomization to complete the inoculation.
Day 0 corresponds to the day of inoculation
- Inoculation is preferable within 30 days of screening though allowed up to 42 days.
STUDY AGENT REQUEST

- Pharmacist’s Prescription List (SID list)
  - FSTRF creates sends to site pharmacist
  - corresponds with treatment assignment
- Subject entered into the SES a SID number will be assigned by FSTRF
  - assigned SID number is sent via email to research staff
  - enrollment confirmation containing SID randomization is forwarded to pharmacist

Source: IMPAACT2013 MOP, Section 5.4.3, v0.2, 24February2017
A prescription for RSV D46/NS2/N/ΔM2-2-HindIII is sent to pharmacist

- SID and PID of the participant
- verification of signed consent
- any other information required by the site and
- must be signed by an authorized prescriber

Notify site pharmacist of the date and time the vaccine/placebo is to be administered

Unblinded pharmacist will use the Pharmacist’s Prescription List to determine if the participant receives active vaccine or placebo
Two-part Syringe label containing:
- IMPAACT 2013 Intranasal RSV or Placebo
- SID _____PID_____
- Expiration date and time
- Staff Initials:_________/_________
- These labels can be purchased from Health Care Logistics – item #6028

Syringe carrier bag label containing participant-specific information:
- Date dispensed
- Participant Name or Identifiers (per site’s SOP)
- Directions: Instill 0.25 mL in each nostril
- IMPAACT 2013 RSV D46/NS2/N/ΔM2-2-HindIII $10^5$ PFU or Placebo nasal vaccine
- 0.5mL/syringe
- Expiration Date and time in 24 hour clock
- Initials of pharmacist preparer and checker
- Authorized prescriber’s name

The syringe carrier bag should be labeled with an auxiliary label stating:
- FOR INTRANASAL ADMINISTRATION ONLY
STUDY AGENT TRANSPORT

- Biohazard Labeled Cooler with wet ice including:
  - min/max thermometer
  - Sealable bag enclosing a syringe case holding:
    - 1 mL syringe with yellow overlay labeled syringe with study product
- Document temperature on the IMPAACT 2013 Study Product Administration Record (SPAR) when cooler leaves pharmacy and reset min/max thermometer
- Keep dose on wet ice till administered to the participant
- Document current, min., and max., temperatures on the SPAR when dose removed from the cooler
- If the cooler not maintained 2-8°C, contact pharmacy for a replacement dose

Source: IMPAACT2013 MOP, Section 5.4.8, v0.2, 24February2017
# STUDY PRODUCT ADMINISTRATION RECORD

**IMPAACT 2013 Study Product Administration Record**

### Section 1: Completed by Pharmacy Personnel

<table>
<thead>
<tr>
<th>Vaccine Name or Matching Placebo:</th>
<th>Total Volume of Dose:</th>
<th>Route of Administration:</th>
</tr>
</thead>
<tbody>
<tr>
<td>D46(N)52/V/v1.2.1m(S2) or V1.1.16</td>
<td>0.5 ml</td>
<td>Intranasal</td>
</tr>
</tbody>
</table>

**Expiration time of Study Product:**

- Date: [ ]
- Time (24-hour clock): [ ]

**Signature of Pharmacist Preparing Study Product**

I have checked the preparation and documentation of this dispensing:

**Signature of Pharmacy Personnel Checking Study Product**

Temperature leaving pharmacy: [ ] °C

### Section 2: Completed by Clinical Personnel

<table>
<thead>
<tr>
<th># of Syringes Received:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signature of Clinician Accepting Study Product</td>
</tr>
</tbody>
</table>

Temperatures prior to administration of study product:

- Current: [ ] °C
- Minimum: [ ] °C
- Maximum: [ ] °C

Note: If temperature is not between 2-8°C, please contact the pharmacy for a replacement dose.

### Section 3: Participant Identifier

<table>
<thead>
<tr>
<th>PID #</th>
<th>Date Given</th>
<th>Study Product Given By (Signature)</th>
</tr>
</thead>
</table>

**Completed by Pharmacy Personnel**

**Completed by Clinical Personnel**

### Section 4: Completed by Pharmacy Personnel

<table>
<thead>
<tr>
<th># of Syringes Returned:</th>
</tr>
</thead>
</table>

**Signature of Pharmacy Personnel Accepting Syringes and/or Form**

*Disposition Code:
- A=Administered
- B=Returned to Pharmacy

**IMPAACT 2013 Manual of Procedures Version 0.2**

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February 24, 2017
IMPAACT 2013 Study Product Administration Record

Vaccine Name or Matching Placebo: D4F(H5N1)AV/02/2006/Eng/1 or D4F(L18)
Study #: IMPAACT 2013 IND #: TBD

Section 1: Completed by Pharmacy Personnel
Expiration time of Study Product:

Date __/__/__ @ __:__ (24-hour clock)

Signature of Pharmacist Preparing Study Product
I have checked the preparation and documentation of this dispensing:

Signature of Pharmacy Personnel Checking Study Product
Temperature leaving pharmacy: ___________ °C

Section 2: Completed by Clinical Personnel
# of Syringes Received: ________

Signature of Clinician Accepting Study Product
Temperatures prior to administration of study product:
current: ___________ °C
minimum: ___________ °C
maximum: ___________ °C

Note: If temperature is not between 2-8°C, please contact the pharmacy for a replacement dose.

Section 3: Participant Identifier
PID #: ___________
Date given: ___________
Study Product Given by (Signature): ___________

Completed by Pharmacy Personnel
Completed by Clinical Personnel

Section 4: Completed by Pharmacy Personnel
# of Syringes Returned: ___________

Signature of Pharmacy Personnel Accepting Syringes and/or Form: ___________ / ___________

*Disposition Code:
A=Administered R=Returned to Pharmacy

Original: STUDY BINDER Copy: PHARMACY

IMPAACT 2013 Manual of Procedures Version 0.2 Page 55 of 61 February 24, 2017
STUDY PRODUCT ADMINISTRATION

Source: CIR Pediatric Group, 2011.
# IMPAACT 2011 Study Product Administration Record

**Section 1: Completed by Pharmacy Personnel**

- **Expiration time of Study Product:**
  - Date: __/__/__
  - Time (24-hour clock): __:__

**Signature of Pharmacist Preparing Study Product**

I have checked the preparation and documentation of this dispensing:

**Signature of Pharmacy Personnel Checking Study Product**

Temperature leaving pharmacy: ____________ °C

**Section 2: Completed by Clinical Personnel**

- **Total Volume of Dose:** 0.5 mL
- **Route of Inoculation:** Intranasal
- **Signature of Clinician Accepting Study Product**

Temperatures prior to administration of study product:
- **current:** ____________ °C
- **minimum:** ____________ °C
- **maximum:** ____________ °C

Note: If temperature is not between 2-8°C, please contact the pharmacy for a replacement dose.

**Section 3: Participant Identifier**

<table>
<thead>
<tr>
<th>Date</th>
<th>Time Given</th>
<th>Study Product Given By (Signature)</th>
<th>Signature below Ensures Correlation between Participant Identifier &amp; PID #</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Disposal of Study Product**

*Disposition Code,*
- A = Administered, B = Returned to Pharmacy, Original = STUDY BINDER, Copy = PHARMACY

**Section 4: Completed by Pharmacy Personnel**

- **# of Syringes Returned:** ____________
- **Signature of Pharmacy Personnel Accepting Syringes and/or Form**
  - Date: __/__/__

---

**Source:** IMPAACT2011,MOP,AppendixVI,v0.4,21April2016
## IMPAACT 2011 Study Product Administration Record

### Section 1: Completed by Pharmacy Personnel

- **Expiration time of Study Product:**
  - Date: ___________
  - Time (24-hour clock): ___________

- **Signature of Pharmacist Preparing Study Product:**
  - I have checked the preparation and documentation of this dispensing.

- **Signature of Pharmacy Personnel Checking Study Product:**
  - Temperature leaving pharmacy: ___________ °C

### Section 2: Completed by Clinical Personnel

- **Total Volume of Dose:** 0.5 ml
- **Route of Inoculation:** Intra nasal

- **Signature of Clinician Accepting Study Product:**
  - Temperatures prior to administration of study product:
    - Current: ___________ °C
    - Minimum: ___________ °C
    - Maximum: ___________ °C

  Note: If temperature is not between 2-8 °C, please contact the pharmacy for a replacement dose.

### Section 3: Participant Identifier

- **PID #:**
- **Date Given:**
- **Time Given:**
- **Study Product Given By:** (Signature)
- **Signature below Ensures Correlation between Participant Identifier & PID #**
- **Disposition of Study Product:**

### Section 4: Completed by Pharmacy Personnel

- **# of Syringes Returned:**
- **Signature of Pharmacy Personnel Accepting Syringes and/or Form:**

---

Source: IMPAACT2011, MOP, Appendix VI, v0.4, 21 April 2016
SNAP/FLASH FREEZING

- Supplies needed
  - CoolBox® with CoolRack®
  - Cooler
  - Dry Ice
  - Specimen or Vaccine
- Demo Snap Freezing

Source: IMPAACT2013,MOP,AppendixV,v0.2,24February2017
SNAP/FLASH FREEZING

Source: JHU, CIR Pediatric Group, 2011.
SNAP/FLASH FREEZING

- Fill CoolBox® dry ice pellets
  - up to the bottom of finger grip recesses
- Place CoolRack® directly on dry ice
  - wait >20 minutes
- Place tightly sealed cryovials in CoolRack®
  - wait >15 minutes
  - cryovials can be transported in CoolBox® with dry ice pellets or transferred to an insulated container with dry ice pellets
    - Container must be able to “breathe” as the dry ice sublimates, creating pressure inside a sealed container
    - Maintain in a well-ventilated area
- Store samples in a -80°C (± 15°C) freezer

Source: IMPAACT2013,MOP,AppendixV,v0.2,24February2017
SNAP/FLASH FREEZING

- Allow dry ice to dissipate in the impervious container
- Do not throw dry ice in the sink
  - Extreme cold (dry ice) will crack the drainage pipe
- Suggested: Keep CoolRack® at <-20 °C freezer when not in use
- Closing the CoolBox® lid
  - will not decrease the CoolRack® temperature
  - Will extend the cooling duration
- Provide the lab with IMPAACT 2013 Specimen Tracking form with processing times completed

Source: IMPAACT2013,MOP,AppendixV,v0.2,24February2017
THANK YOU!!!