Module 1

IMPAACT 2000 Investigator’s Meeting
August 29, 2014
Protocol IMPAACT2000: RSV LID Δ M2-2

Enrollment: Randomization & Inoculation
Enrollment & Inoculation - Day 0

Recruitment  Consent  Screening  Enrollment  Inoculation  Study Visit  RSV Seasonal Surveillance
Enrollment & Inoculation Day

- Nasal wash
- Clinical assessment: inoculation plus 10 visits
- Screening
- Nasal immunization

Randomization

- Subjects must meet all the inclusion
- Subjects must not meet any of the exclusion criteria
- Enroll in IMPAACT 2000 by utilizing the Subject Enrollment System (SES)
  - located on the IMPAACT DMC website and [www.fstrf.org](http://www.fstrf.org)
- 2:1 ratio of RSV LID ΔM2-2, Lot RSV #0007A 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

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 is sent via email to research staff
  - Enrollment confirmation containing SID is forwarded to pharmacist
Study Agent Request (continued)

- A prescription for RSV LID ΔM2-2 vaccine or placebo containing 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
Study Product Labeling

- **Two-part Syringe label containing:**
  - IMPAACT 2000 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 2000 RSV LID ΔM2-2 105.0 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

Supplies Needed for Vaccine Transport

- Biohazard Labeled Cooler with wet ice including
  - min/max thermometer
  - Sealable bag enclosing a syringe case holding
    - 1 mL amber colored labeled syringe with study product

- Product Administration Record (PAR)
Product Administration Record

IMPAACT 2000 Study Product Administration Record

| Vaccine Name or Matching Placebo: RSV LID AME-2 vaccine or 1×L-15 |
| Study #: IMPAACT 2000 IND #: 15713 |

| Total Volume of Dose: 0.5 mL |
| Route of Inoculation: Intranasal |

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: [Temperature] °C

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

Signature of Clinician Accepting Study Product
Temperatures prior to administration of study product:
current: [Temperature] °C
minimum: [Temperature] °C
maximum: [Temperature] °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*

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 [Date]

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

# Product Administration Record

![IMPAACT 2000 Study Product Administration Record](image)

Product Administration Record

**IMPAACT 2000 Study Product Administration Record**

- **Vaccine Name or Matching Placebo:** RSV LID AM2-2 vaccine or 1X L-15
- **Study #:** IMPACT 2000
- **IND #:** 15713
- **Total Volume of Dose:** 0.5 mL
- **Route of Inoculation:** Intranasal

**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: [Temperature] °C

**Section 2: Completed by Clinical Personnel**

- **# of Syringes Received:** [Number]
- **Signature of Clinician Accepting Study Product**
- **Temperatures prior to administration of study product:**
  - Current: [Temperature] °C
  - Minimum: [Temperature] °C
  - Maximum: [Temperature] °C

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

**Section 3: Participant Identifier**

- **PID #**

- **Completed by Pharmacy Personnel**

**Section 4: Completed by Pharmacy Personnel**

- **# of Syringes Returned:** [Number]
- **Signature of Pharmacy Personnel Accepting Syringes and/or Form** [Date]

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

Study Product Administration

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

### IMPAACT 2000 Study Product Administration Record

<table>
<thead>
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<td>Expiration time of Study Product:</td>
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Note: If temperature is not between 2-8°C, please contact the pharmacy for a replacement dose.

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*Disposition Code: A=Administered R=Returned to Pharmacy Original - STUDY BINDER Copy - PHARMACY

# Product Administration Record

**IMPAACT 2000 Study Product Administration Record**

**Vaccine Name or Matching Placebo:** RSV LID, ADZ-2 vaccine or 1X L-15

**Study #: IMPAACT 2000**  
**IND #: 15713**

**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**

- PID #
- Date Given
- Time Given
- Study Product Given By (Signature)

**Signature below Ensures Correlation between Participant Identifier & PID #**

**Disposition of Study Product**

Disposal Code:

- A = Administered
- R = Returned to Pharmacy

**Section 4: Completed by Pharmacy Personnel**

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

**Completed by Pharmacy Personnel**

**Completed by Clinical Personnel**

![Product Administration Record Image]

Snap/Flash Freezing

Source: JHU, CIR Pediatric Group, 2011.
Snap/Flash Freezing

❖ Supplies needed
  ❖ CoolBox® with CoolRack®
  ❖ Cooler
  ❖ Dry Ice
  ❖ Specimen or Vaccine

❖ Demo
Snap/Flash Freezing

- Fill CoolBox® cavity with pulverized dry ice
  - up to the bottom of finger grip
- Place CoolRack® directly on dry ice
  - wait >20 minutes
- Place tightly closed 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

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
  - 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