
# Study Conduct Best Practices

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# Importance of High-Quality Study Conduct

**Our collective goal:** successfully develop a new treatment for an indication with an unmet need, while ensuring that each study participant receives the highest level of medical care and attention.

## Priovant

- Daily review of each patient's disease progression data (labs, patient and investigator assessments), to flag any patients who may be at risk of worsening disease
- 24/7 availability to assist sites in addressing AEs, AESIs, and SAEs that patients may experience
- 24/7 availability (on-site and virtual support) to assist sites with data entry and study conduct questions/issues

## Site

- Proactive identification of patients who may need rescue or be at risk of study discontinuation
- Open communication with sponsor team regarding at-risk patients
- 100% data entry completion within 48-72 hours of every study visit
- Adherence to sponsor-provided study conduct best practices

# What we ask of you coming out of this session…

1. Your attention and participation to best practices will directly impact the success of this trial and our ability to deliver new therapies to patients with DM
2. Accurate and timely data entry is essential
3. Ensure patient questionnaires are performed correctly and accurately
   - HAQ, PtGA-VAS
4. Perform the TB test correctly
5. Use the proper tools for shipping samples
6. Make sure that all SUSARs are reviewed, acknowledged, and filed in the ISF

# Data Entry

# Data Entry Expectations

| Expectation | Why it's important |
| --- | --- |
| • Data entered within 48-72 hours after each study visit (including any medication changes)<br>• Adverse events and any associated medications/procedures entered within 48 hours<br>• Timely and routine query closing (within 1 week of queries being raised) | • Priovant Medical and Clinical teams review patient data to identify any patients who are at risk and ensure protocol adherance.<br>• The faster data is uploaded, the more prepared the sponsor team can be to ensure patient safety.<br>• The Priovant Clinical Monitoring team is working diligently to make sure that your site is up to date with all documentation, to ease your site's query backlog burden during interim data collection and study closeout activities |

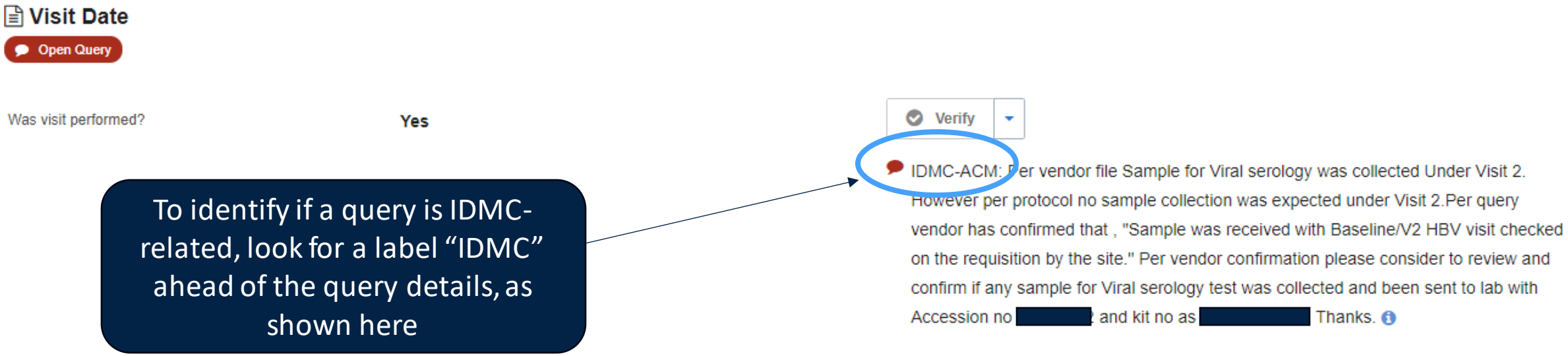
# Tips for Prioritizing Queries to Address

1. Start with any queries of interest:
   - Safety, Eligibility, Steroid Taper, Rescue, Potential Protocol Deviations
2. Queries related to IDMC
3. Prioritize all queries aging >60 days
4. Work from oldest to newest open queries

**If any study team member is spending more <u>than 45 seconds</u> trying to figure out what a query is asking, reach out to your site's CRA for a quick response.**

# Example of data entry best practices – IDMC queries

- VALOR's Independent Data Monitoring Committee (IDMC) meets every 3 months to review study data and ensure safety of clinical trial participants
- Open data queries related to an upcoming IDMC meeting are critical to close within 48 hours, as the data points in question are being reviewed by the independent committee with heightened attention for patient safety
- **Site review of open queries multiple times a week is vital to ensure that these queries are addressed within the required time frames. If you ever have any questions about the query, our CRAs are always happy to help!**



# Data entry best practices – prioritizing aging queries

- CRAs will routinely send each site a list of open queries organized by date, like this example below.
- Prioritize closing out queries with the **most days unresolved**, first.

| Folder | Form | Field | Log # | Query Status | Qry Open Date | Query Text | Days Unresolved |
|---|---|---|---|---|---|---|---|
| COMMON | Dermatomyo | CM2ENDAT | 6 | Answered | 08 Jun 2023 | As per guidelines, at a minimum, a Year must be provided w | 225 |
| SCREENING | CT Scan | SCNDAT | 0 | Answered | 31 Oct 2023 | Please verify results are "normal" as EMR report states "Mil | 90 |
| COMMON | Prior And Co | CPPRO | 3 | Answered | 02 Nov 2023 | Per EMR please confirm if the following should be added: B | 90 |
| SCREENING | Physical Exan | PEPERF | 0 | Answered | 02 Nov 2023 | Please provide source, no source in subject binder | 90 |
| COMMON | Prior and Co | CPYN | 0 | Answered | 01 Nov 2023 | Per EMR please confirm if endometrial ablation should be a | 90 |
| SCREENING | Standard 12- | EGRS | 0 | Answered | 01 Nov 2023 | Per Banook report, CS Right Bundle Branch Block on ECG. N | 84 |
| VISIT 6 (WEE | Health Asses | HAQDIQ4I | 0 | Answered | 01 Nov 2023 | Per source with some difficulty | 84 |
| VISIT 6 (WEE | Health Asses | HAQDIQ4J | 0 | Answered | 01 Nov 2023 | per source without any difficulty | 84 |
| VISIT 6 (WEE | Health Asses | HAQDIQ4K | 0 | Answered | 01 Nov 2023 | per source with some difficulty | 84 |
| SCREENING | Physician Gl | PHGARI | 0 | Answered | 01 Nov 2023 | Please have physician date the correction on the source. | 84 |
| VISIT 4 (WEE | Patient Globa | PTGIC01 | 0 | Answered | 01 Nov 2023 | Patient chose both no change and slightly worse on source. | 62 |
| COMMON | Drug Accoun | DAVISD | 3 | Answered | 01 Nov 2023 | Please add log lines for IP dispensed Aug 17 and Sept 27 alc | 56 |
| SCREENING | Physical Exan | PERES | 4 | Answered | 31 Oct 2023 | Source not updated. Refer to encounter note dated 24Aug2 | 49 |
| SCREENING | 2017 EULAR/ | EUP1PP | 12 | Open | 13 Dec 2023 | Was EULAR/ACR Idiopathic Inflammatory Myopathies asse | 49 |
| SCREENING | 2017 EULAR/ | EUP1CTR | 11 | Open | 14 Dec 2023 | Please verify if assessed and update on source and in EDC. | 48 |
| SCREENING | Myositis Dise | MDATCUDA | 0 | Answered | 14 Dec 2023 | Per source and measurement, this is 3.7cm. Please verify a | 48 |
| SCREENING | Vital Signs | VSTEMP | 0 | Answered | 15 Dec 2023 | Per EMR, temperature is 85 and pulse is 98.9. These appea | 47 |

# Data Entry Best Practices – Steroid Taper Entry

As per the earlier sessions at the Investigator Meeting, the steroid taper is a critical component of our study protocol.

<table>
<tr><th>BEFORE WEEK 12</th><th colspan="2">WEEK 12 – WEEK 36</th><th>WEEK 36 – WEEK 52</th></tr>
<tr><td rowspan="4">Remain on stable baseline dose of prednisone (≤ 20 mg/day or equivalent)</td><td colspan="2">Prednisone should be tapered to ≤ 5 mg/day (or equivalent).<br>Tapering dose below 5 mg/day is permitted at investigator's discretion.</td><td rowspan="4">Prednisone dose should be stable at ≤ 5 mg/day (or equivalent).</td></tr>
<tr><td>Stable daily dose at Week 12</td><td>Tapering schedule to 5mg/day</td></tr>
<tr><td>> 10 and ≤ 20mg</td><td>Taper 2.5 mg every 2 weeks to 5 mg/day</td></tr>
<tr><td>≤ 10 mg</td><td>Taper 2.5 mg every 4 weeks to 5 mg/day</td></tr>
</table>

There are up to 2 eCRF pages relevant to the steroid taper that should be entered within 72 hours of the study visit.

1. Corticosteroid Tapering eCRF = This documents whether a reduction in CS occurred at that visit
2. DM Concomitant Medication Log = If there was a change in dose, the new dose should be documented here.

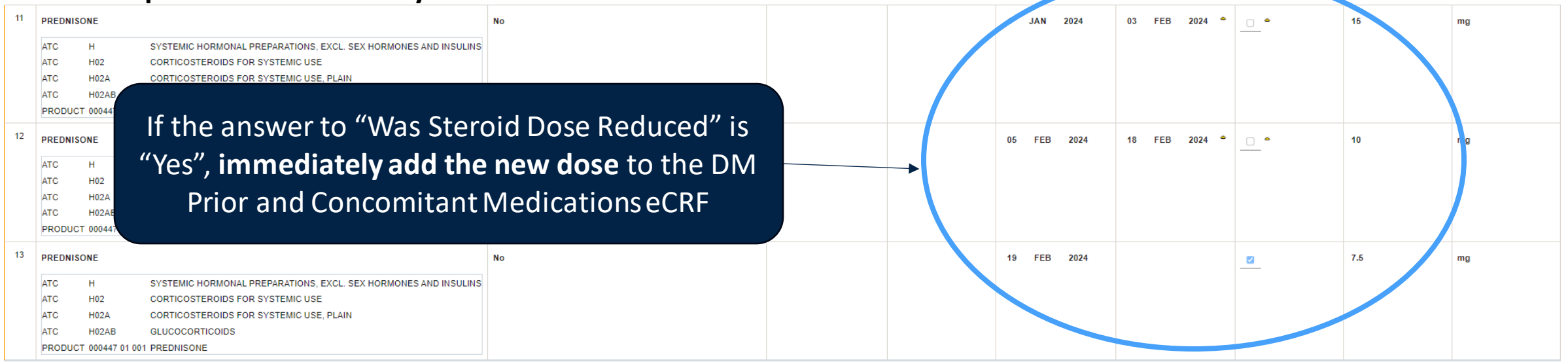
# Example of Data Entry Best Practices – Steroid Taper Entry

## 1. Update "Corticosteroid Tapering" eCRF from V5 to V9


Answer "Yes" if patient is at a dose less than or equal to 5 mg/day **at the visit in question**

Answer "Yes" if patient's dose was reduced **at the visit in question**

## 2. Enter Updates in Dermatomyositis Prior and Concomitant Medications




If the answer to "Was Steroid Dose Reduced" is "Yes", **immediately add the new dose** to the DM Prior and Concomitant Medications eCRF

# Example of data entry issues – MDAAT partially-entered


The most commonly missed data points are in the 2017 EULAR Assessment performed at screening, and the MDAAT.

**Please ensure all investigator assessments are fully answered before the investigator leaves the room.**

# EDC – Clinical Worsening CRF

Upcoming EDC update: CW CRF will only indicate whether the calculations of each criterion meet or does not meet the criteria. If the calculations meet criterion and if a participant requires a single burst of corticosteroids (before Week 12) or a rescue (after Week 12), indicate the change of medication in the Dermatomyositis Prior and Concomitant Medications CRF.

| | Prior Visit | This Visit | Derived Message |
|---|---|---|---|
| **V3 and V4** | NA | Yes | The participant meets clinical worsening at this visit. If needed, a single course of corticosteroids is permitted, and if dosed, the Dermatomyositis Prior and Concomitant Medications eCRF should be completed. |
| **V3 and V4** | NA | No | The participant does not meet clinical worsening at this visit. |
| **V5 and beyond** | Yes or No | No | The participant does not meet clinical worsening at this visit. |
| **V5 and beyond** | Yes | Yes | The participant meets clinical worsening at this visit and the prior visit. If needed, rescue therapy is permitted, and if dosed, the Dermatomyositis Prior and Concomitant Medications eCRF should be completed. |
| **V5 and beyond** | No | Yes | The participant meets clinical worsening at this visit but not the prior visit. Rescue therapy is not permitted, please reach out to Medical Monitor. |
| **V5 and beyond** | Yes (diff criterion) | Yes (diff criterion) | The participant meets a different clinical worsening criterion at this visit from the prior visit. Rescue therapy is not permitted, please reach out to Medical Monitor. |
| **UNS** | N/A | Yes | The participant meets clinical worsening at this visit. Before Visit 5 (Week 12), a single course of corticosteroids is permitted, if needed. After Visit 5 (Week 12), rescue therapy **(if needed)** is permitted if same clinical worsening criteria is met at two consecutive visits 3 weeks apart. For all rescue medications, complete the Dermatomyositis Prior and Concomitant Medications eCRF. |
| **UNS** | N/A | No | The participant does not meet clinical worsening at this visit. |

# EDC – Rescue Therapy

Any change in medication, including rescue therapy, should be captured in the Dermatomyositis Prior and Concomitant Medications CRF

Is this a rescue medication during the Blinded Treatment Period? **Yes** or **No**

If Yes, you must choose reason for rescue therapy:

- **Met clinical worsening criteria**
- **Did not meet clinical worsening criteria but needed rescue** → Specify the reason for the rescue needed in free text. Enter symptoms, lab changes, or specific conditions that warranted a rescue therapy.

# Patient Questionnaires

# Questionnaire Organization

- **Please reference the schedule of activities in the protocol 1 week prior to each study visit to ensure that the correct investigator and patient questionnaires are provided to PIs and participants at each visit.**
- If missing documentation:
    1. Pull extra questionnaires from the end of the supplementary binder to ensure that all necessary questionnaires are completed
    2. Contact your site's CRA to troubleshoot the issue and order additional documentation

Example:
- Subject 10-111-1111 is coming in for V4 next week.
- Upon review of the schedule of activities, 10-111's study coordinator discovers that they are missing the CDASI Investigator Questionnaire in this packet

Solution:
- Pull an extra CDASI questionnaire from the extras located at the end of the supplementary binder and incorporate into the visit packet
- Contact 10-111's monitor to inform of the issue
    - Monitor will ask additional questions to identify if documents are missing from other visits (e.g V6, V8, V10) and will ensure that new questionnaires are shipped to the site.

# Patient Reported Outcomes – Best Practices

1. On average, it can take approximately 15-20 minutes to complete all PROs
2. Please provide the PROs to the patient in the order of the timeframe they need to considering, when answering the questions e.g.:
   I. PRO tools: PtGA skin, muscle, pain, swallow, flexibility, S (**today**)
   II. PtGlobal Disease (**today**)
   III. PP-NRS (previous **24 hours**)
   IV. FACIT Fatigue (past **7 days**)
   V. HAQ (over the **past week**)
   VI. PtGI-C (**since starting medication**)
   VII. SF-36 (**1 year ago and past 4 weeks**)

**All of the forms for both the Physician and the Patient assessments can be found organized by study weeks in the Supplementary Binder provided to each site**

# Patient Reported Outcomes – Best Practices

## Patient accuracy of the assessments is critical, particularly the **Health Assessment Questionnaire (HAQ)**

We ask for your support in following some best practices while the patient fills out each PRO to ensure the forms are completed accurately:

1. Please remind the patient of the importance of completing these accurately. The patient should be aware of the concept of questionnaire fatigue.
2. Please sit with the patient while they complete each questionnaire. They should be provided to the patient one at a time.
3. Prior to completing each PRO, read the instructions out loud to the patient to ensure they understand the time point they need to consider for their answers
4. Once the PROs are completed, **review them with the patient**:
   - Have they left any questions blank?
   - Are there any discrepancies?
   - Were there any questions on the form the patient did not understand?
5. Confirm that the response reflects how the patient feels, without biasing the patient.
   - Full comprehension of what the questionnaire is measuring, and that pt has answered appropriately

# HAQ/Patient Global VAS Divergence

**Example 1: Unstable Patient Global VAS, while HAQ disability score stays stable**

**Issue:**

- Subject 88-777-6666's HAQ Disability Score was reported as a 2.34/3 at V6. This indicates that their disease is causing a significant impact to their daily life in this past week.
- Their Patient Global Activity – Visual Analog Scale results were reported as a 1.1/10 at V6, indicating that their disease activity is mild on the day of the visit.
- **What do you observe about the trends below and the data at V6?**
- **What actions should you take at each visit to ensure integrity and accuracy of this participant's answers?**

| Visit | PtGA-VAS |
|---|---|
| V2 | 7.2 |
| V3 | 4.9 |
| V4 | 2.8 |
| V5 | 2.7 |
| V6 | 1.1 |

| Visit | HAQ |
|---|---|
| V2 | 1.88 |
| V3 | 1.00 |
| V4 | 1.05 |
| V5 | 0.95 |
| V6 | 2.34 |

# HAQ/Patient Global VAS Divergence

**The Health Assessment Questionnaire and Patient Global Activity – VAS are the most important patient-reported outcomes questionnaires for this study, as they directly factor into the study's primary endpoint, the TIS**

**Resolution:**

- In this example, the patient's report of their disability within the past week has gotten worse, while their analysis of their current disease activity burden shows that they are only experiencing mild symptoms.
- After the questionnaires are completed, sit with the patient and review their answers. If any discrepancies are noticed, these can be pointed out as facts, i.e:
  - "Your HAQ score implies that you've seen worsening of your disability this past week, but the PtGA-VAS indicates improvement of your overall disease activity today. Does this reflect how you are feeling today?"
  - If the patient says "yes, this is accurate" – great. If they feel that their score is inaccurate base on the clarification of what their answers mean, they can change their scores while they are still in clinic for their visit.

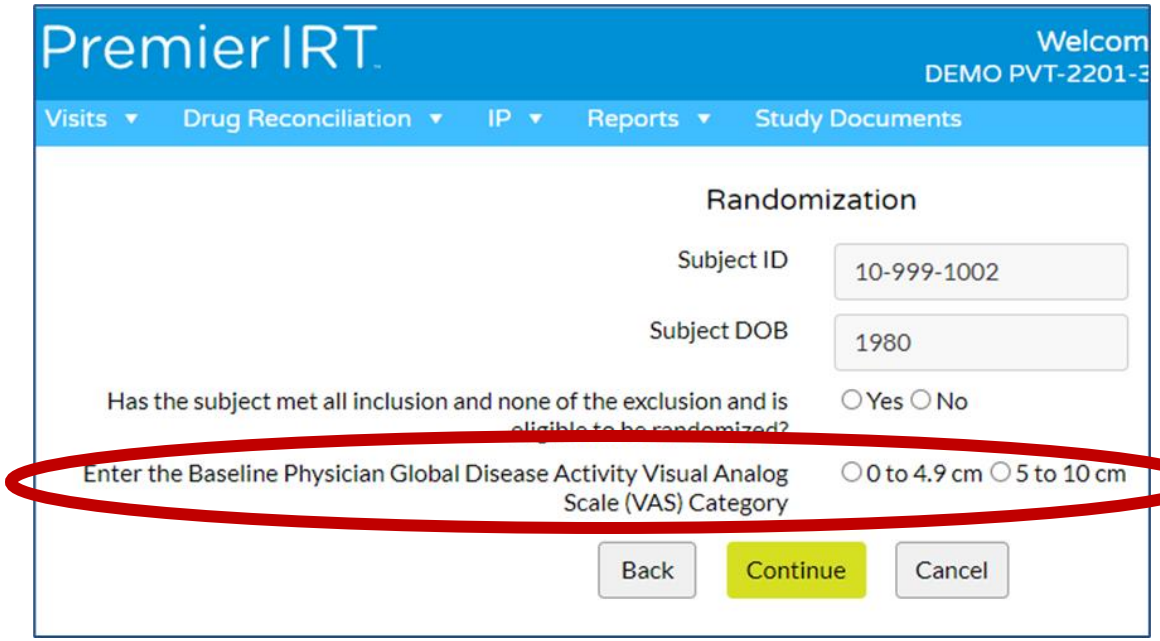
| Visit | PtGA-VAS |
|---|---|
| V2 | 7.2 |
| V3 | 4.9 |
| V4 | 2.8 |
| V5 | 2.7 |
| V6 | 1.1 |
| V7 | 0.8 |

| Visit | HAQ |
|---|---|
| V2 | 1.88 |
| V3 | 1.00 |
| V4 | 1.05 |
| V5 | 0.95 |
| V6 | 2.34 |
| V7 | 0.88 |

# IRT and IP Best Practices

# IRT Randomization – Patient Stratification

## When randomizing subjects in the IRT, the BASELINE PhGA-VAS score must be entered




- At randomization, the IRT prompts the site to enter in the Physician Global Disease Activity Visual Analog Scale (VAS) Category
- This applies to the assessment **at V2**, not at V1
- Prior to randomization, please use the study-provided ruler to measure the investigator's assessment and enter this into the IRT

- *This ensures that patients whose disease activity has gotten worse, or improved, since screening are stratified correctly into the study*

# IP Best Practice – Dosing at the Study Visit

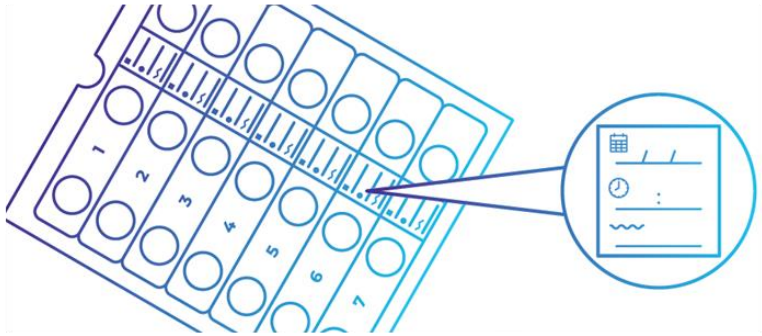
**In-clinic doses: V2, V3, V7, V12 (if participant is rolling over into OLE)**

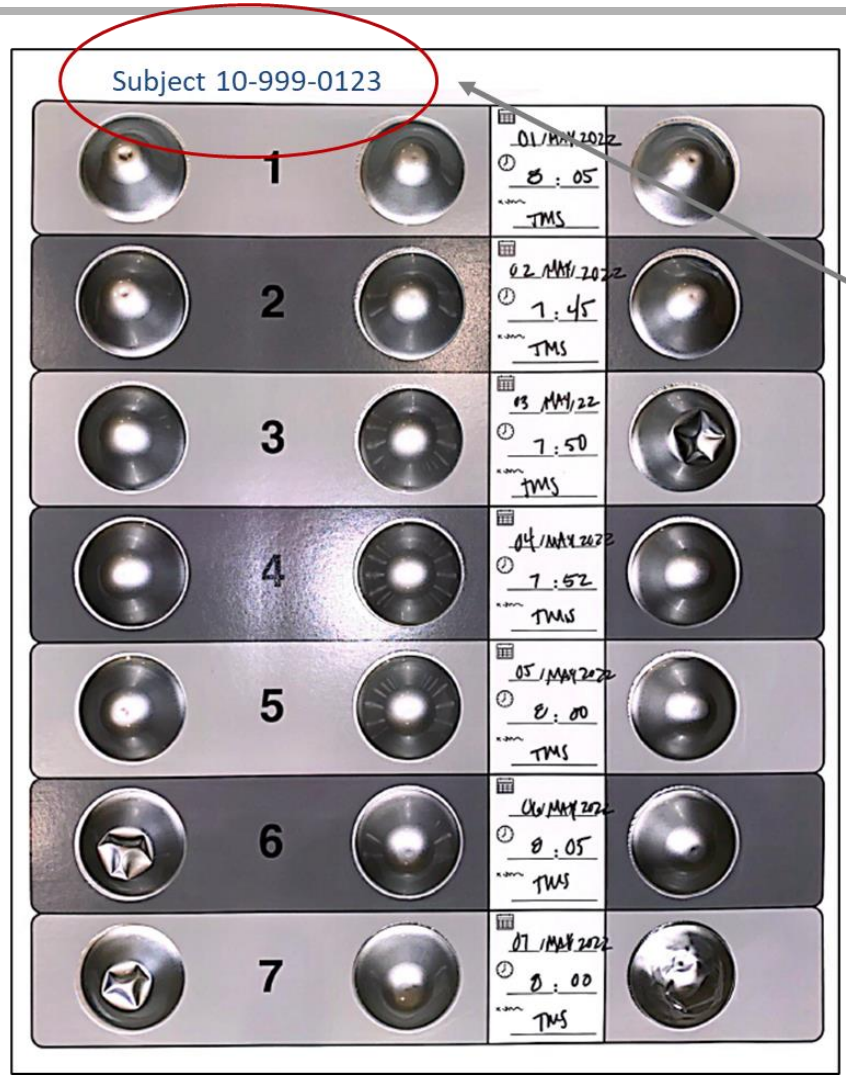
- ☑ Please contact subjects 1-2 days prior to their upcoming visit
- ☑ Remind them to hold off on taking their daily IP until arriving in clinic for their scheduled study visit
- ☑ This ensures accurate records of IP dosage timing for PK sample draws

# IP Best Practice – Keep Records of Returned IP Kits

A photocopy of the blister card containing participant dosing record should be filed in the source.

Participants should be instructed to record the date, time and their initials with each dose.






Include the Subject ID when saving the photocopy to the source charts.

# Lab Samples

# **Best Practice:** Confirm Lab Kit Supply At Least 2 Weeks Prior to Study Visit

To prepare for every study visit, confirm that you have sufficient, non-expired lab kits and additional supplies to cover all specimen collections

**Visit Kits**

Please reference Lab Manual Section 1.5 (Laboratory Supplies) at least 2 weeks prior to every study visit to ensure that the necessary kits are:

1. **On-site**
2. **Not at risk of expiration**

**Other Supplies**

- Validated 2-8°C Nanocooler
- Frozen Aliquot Box
- Thermosafe Coolers with dry ice markings
- Ambient Sample Packaging
- Ambient/Frozen Airbills

If you need any of the above supplies, you can re-order them through ACM: https://labstar.acmgloballab.com. **Note that lab kits may take up to 2-3 weeks to arrive on site**

**Even if you don't have the necessary supplies in the 2 weeks prior to any study visit, do not cancel the visit. Reach out to Priovant and we will identify a solution that does not delay the patient's study participation/cause protocol deviations**

# Correct lab sample processing is critical!

Mistakes lead to delays, repeated patient visits and draws, and more work for you

1. Inaccurate labeling of lab samples leads to DIFs and AIs – unnecessary work for you
2. TB lab processing is the #1 reason for randomization delays and patient burden
3. Improper packaging and shipping wastes the patients time and effort, increases burden for patients and site staff, and delays the start of the study for the patient

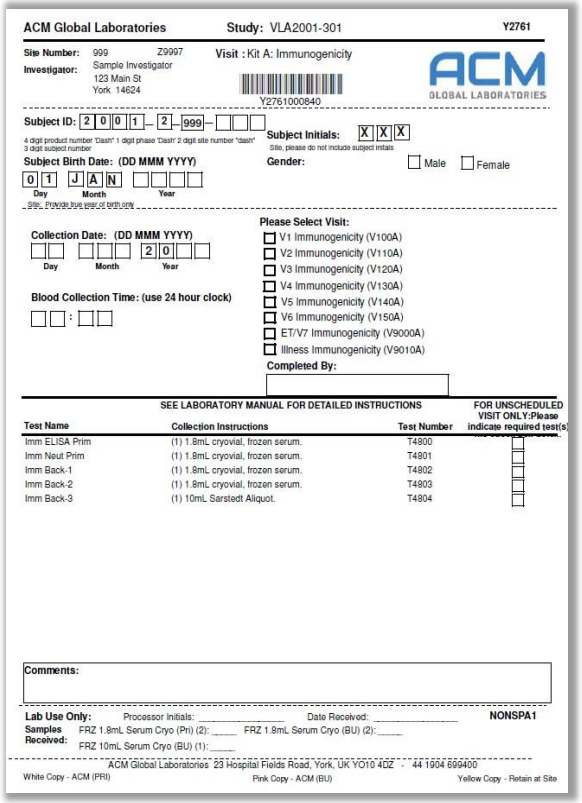
**Be sure the personnel managing lab samples are properly trained**

**If you have questions about lab samples – call your Priovant (Drew, Sabrina, Scott)**

# Sample Labelling and Requisitions

## Requisition Details

- Complete legibly and accurately
- All samples must include a requisition form within the shipment
- **Ensure ALL elements of requisition are complete (e.g. subject age and gender; fasting status [no fasting required for any VALOR lab draws])**



ACM Global Laboratories Study: VLA2001-301 Y2761

Site Number: 999 Z9997 Visit : Kit A: Immunogenicity
Investigator: Sample Investigator
123 Main St
York 14624

Y2761000840

Subject ID: 2 0 0 1 – 2 – 999 – _ _ _
4 digit product number "Dash" 1 digit phase "Dash" 2 digit site number "dash" 3 digit subject number

Subject Initials: X X X
Site, please do not include subject initials

Subject Birth Date: (DD MMM YYYY) 0 1 J A N _ _ _ _
Day Month Year
Site: Provide true year of birth only

Gender: ☐ Male ☐ Female

Collection Date: (DD MMM YYYY) _ _ _ _ _ _ 2 0 _ _
Day Month Year

Blood Collection Time: (use 24 hour clock) _ _ : _ _

Please Select Visit:
- ☐ V1 Immunogenicity (V100A)
- ☐ V2 Immunogenicity (V110A)
- ☐ V3 Immunogenicity (V120A)
- ☐ V4 Immunogenicity (V130A)
- ☐ V5 Immunogenicity (V140A)
- ☐ V6 Immunogenicity (V150A)
- ☐ ET/V7 Immunogenicity (V9000A)
- ☐ Illness Immunogenicity (V9010A)

Completed By:

SEE LABORATORY MANUAL FOR DETAILED INSTRUCTIONS

| Test Name | Collection Instructions | Test Number | FOR UNSCHEDULED VISIT ONLY:Please indicate required test(s) |
|---|---|---|---|
| Imm ELISA Prim | (1) 1.8mL cryovial, frozen serum. | T4800 | ☐ |
| Imm Neut Prim | (1) 1.8mL cryovial, frozen serum. | T4801 | ☐ |
| Imm Back-1 | (1) 1.8mL cryovial, frozen serum. | T4802 | ☐ |
| Imm Back-2 | (1) 1.8mL cryovial, frozen serum. | T4803 | ☐ |
| Imm Back-3 | (1) 10mL Sarstedt Aliquot. | T4804 | ☐ |

Comments:

Lab Use Only: Processor Initials: _____ Date Received: _____ NONSPA1
Samples Received: FRZ 1.8mL Serum Cryo (Pri) (2): ____ FRZ 1.8mL Serum Cryo (BU) (2): ____
FRZ 10mL Serum Cryo (BU) (1): ____

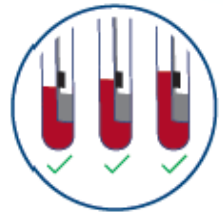
ACM Global Laboratories 23 Hospital Fields Road, York, UK YO10 4DZ - 44 1904 699400
White Copy - ACM (PRI) Pink Copy - ACM (BU) Yellow Copy - Retain at Site

**Tubes are pre-labelled, but subject ID must be written on the label prior to packaging**

# QuantiFERON TB Test Processing Best Practices

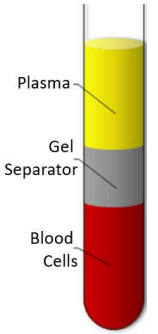
**IMPORTANT: follow the lab manual precisely for collection and handling of QuantiFERON-TB Gold Plus Tests. Ensure the following to prevent collection and testing errors:**

- ☑ All tubes are at room temperature and properly filled with **the blood meniscus falling within the black bar on the label**



- ☑ All tubes are **fully inverted 7 - 10 times after collection** (NOTE: do not vigorously shake tubes as that may cause gel disruption) and **incubated for 16-24 hours at 37 ± 1 º C**

- ☑ All tubes are centrifuged at 2,000-3,000 RCF (g) **for 15 minutes.** If the gel plug did not separate from the plasma, re-centrifuge




- ☑ All tubes are shipped in **approved, ACM-provided NanoCoolers or Pelican coolers.** DO NOT SHIP SAMPLES IN PACKAGING OTHER THAN SPECIFIED IN THE LAB MANUAL

# Sample Packaging and Shipping – QuantiFERON TB

| STEP 1 | STEP 2 | STEP 3 | STEP 4 |
|---|---|---|---|
|  |  |  |  |
| Open the package and remove the item with the silver foil. Press straight down on the actuator button with thumb. | Ensure the NanoCool logo has turned blue, indicating cooling action has begun. Confirm cooling action by touching the surface. | Place the labelled refrigerated samples in the main compartment of 95 kPa biohazard bag. | Place the completed requisition form into the rear compartment of 95 kPa biohazard bag. |
| **STEP 4** | **STEP 5** | **STEP 6** | |
|  |  |  |  |
| Remove the tape liner and seal the 95 kPa biohazard bag. | Place the 95kPa biohazard bag into the insulated payload compartment. | Replace the cooler in its original position in the box. Press firmly to ensure a snug fit. | Close the package and insert the flaps. Tape the lid shut in the appropriate locations. |

# Sample Packaging and Shipping -- Ambient

| STEP 1 | STEP 2 | STEP 3 |
|---|---|---|
|  Place the labeled ambient samples in the main compartment of 95 kPa biohazard bag. |  Place the completed request form into the rear compartment of 95 kPa biohazard bag. |  Remove the tape liner and seal the 95 kPa biohazard bag. |
| **STEP 4** | **STEP 5** | **STEP 6** |
|  Wrap gel pack at room temperature around the samples. |  Place the specimen bag wrapped in gel pack in the ambient shipping box and close. |  Place the box in the UN3373. Pack and seal. |

**Ambient sample maximum stability: 72 hours**

**Pick-up should be on the same day as specimen collection**

# Sample Packaging and Shipping -- Frozen

## STEP 1


Place the labeled frozen samples in the main compartment of 95 kPa biohazard bag.

## STEP 2

Place the completed request form into the rear compartment of 95 kPa biohazard bag.

## STEP 3


Remove the tape liner and seal the 95 kPa biohazard bag.

## STEP 4

Place the samples in the cooler and cover in dry ice.

## STEP 5

Place cover on the cooler (DO NOT tape cooler closed). Complete "Shipper's Information". Affix airbill on top of box designated area.

**Ensure dry ice is available on-site prior to study visit**

**Pick-up should be on the same day as specimen collection**

# Safety Acknowledgements

# Best Practices: SUSARs

## SUSARs: Suspected Unexpected Serious Adverse Reaction

- Immediately after each site is activated, the study team receives a Safety Gap Pack containing all SUSARs issues since the last IB edition was released
- Throughout the study, sites will be receiving individual safety reports from the sponsor team via email

- When each safety gap pack OR individual safety report is received:
    1. **Ensure PI reviews and acknowledges receipt of each report via e-mail**
    2. **Print the report and the acknowledgement and file in the ISF**

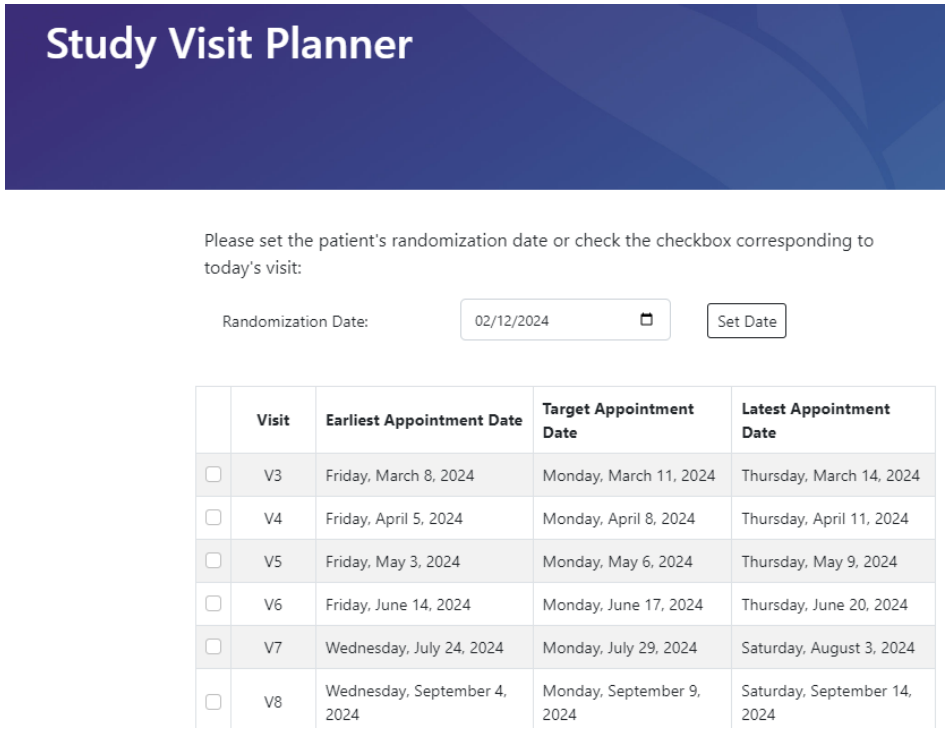
# Patient Retention

# Planning ahead can help to alleviate the stress of 12 visits over 52 weeks

## Proactive scheduling and support for a participant's other commitments can alleviate potential issues

- Some patients struggle with the visit schedule and frequency of visits
  - Every four weeks through V5 (week 12)
  - Every six weeks through V12 (week 52)
- Plan the full 12-visit schedule with the patient before randomization
  - Use VALOR Visit Calculator
  - Discuss which dates work best for the patient within the allowed windows
  - Can adjust the date of randomization by a few days to avoid challenging dates for the patient
  - Utilize the "VALOR Study Schedule and Planner" to write out each visit date on hard copy for each patient.
- Full trial scheduling allows for patients to
  - Visualize their experience in advance
  - Avoid any scheduling issues with holidays, vacations, events
  - Feel in control of their experience

**Plan the upcoming year with patients so they can prioritize the trial visits**




| | Visit | Earliest Appointment Date | Target Appointment Date | Latest Appointment Date |
|---|---|---|---|---|
| ☐ | V3 | Friday, March 8, 2024 | Monday, March 11, 2024 | Thursday, March 14, 2024 |
| ☐ | V4 | Friday, April 5, 2024 | Monday, April 8, 2024 | Thursday, April 11, 2024 |
| ☐ | V5 | Friday, May 3, 2024 | Monday, May 6, 2024 | Thursday, May 9, 2024 |
| ☐ | V6 | Friday, June 14, 2024 | Monday, June 17, 2024 | Thursday, June 20, 2024 |
| ☐ | V7 | Wednesday, July 24, 2024 | Monday, July 29, 2024 | Saturday, August 3, 2024 |
| ☐ | V8 | Wednesday, September 4, 2024 | Monday, September 9, 2024 | Saturday, September 14, 2024 |

# Supporting patients with travel to the site improves retention

## Identify those patients who have mobility issues or travel a long distance for support

- Travel to and from the site can be difficult for some patients
  - Those with mobility issues
  - Those traveling a long distance (in their opinion)
  - Those without caretaker support
- Priovant offers travel support and reimbursement via Elligo/ClinEdge
  - Patients +1 can have travel arrangements made for them or be reimbursed
  - Car service, flights, hotels can be arranged in advance to avoid OOP
  - Meals, mileage can be reimbursed via the RealTime portal

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- If you need assistance with Elligo, please contact Scott, Drew (LATAM), Sabrina (US/CAN) for more details
- If you offer your own travel support, please ensure your patients have access

**Identify which patients may need travel support and be sure they take advantage of the support**

# Exercise Regimen

# Best Practice: Exercise Regimen Stability

**It is vital that patients utilizing physical therapy or an exercise regimen remain on a steady regimen throughout the entire study**

**At or prior to V1:**

- Ask the participant about any exercise or physical therapy regimen at the start of the study
- Document this regimen in the EDC
- Inform the patient that they should maintain this regimen throughout the course of the study
    - Priovant can provide support for maintaining an exercise regimen that starts prior to screening

**At each study visit:**

- Remind patient to maintain the same exercise regimen that was in place prior to randomization
- Remind patient to avoid strenuous activities outside their normal routine during the week prior to each visit
- Document any changes to exercise regimen if they occur throughout the study

# Photography

# Best Practice: Photography

## Photography is an important way to evaluate patients' skin symptoms over time

**Photography at study visits:**

1. Sites should conduct photography in line with their process for photography in the normal clinic setting
    - Camera (smartphone or institutionally-approved camera)
    - File storage (USB, EMR, etc)
    - Patient consent (if separate from your institution's standard ICF)
2. If photography is conducted at baseline (V2), photos should be taken at every ensuing study visit
    - Please follow the same lesions or rashes throughout the course of the study from baseline to completion
    - If possible, ensure that the patient is not identifiable in these photos
3. Photos should be stored via your institution's approved process; sponsor will collect these photos at the close of the study
4. Additionally, sites should print each photo for filing in each subject binder

**We strongly encourage your participation and appreciate your support!**


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