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INVESTIGATOR'S MEETING

August 2 – 3, 2023

Atlanta, GA

AGENDA – DAY 2 MORNING

Topic	Presenter	Time
Re-Cap of Day 1	Paul Wannamaker	9:00 -9:30
Protocol Overview	Chelsea Macfarlane	9:30 – 10:00
Immunology	Elizabeth Wonderlich	10:00 – 10:30
Break	All	10:30 – 10:45
ePROs	IQVIA and Christina Donatti	10:45 – 11:15
Implementation Science Overview	Cassidy Gutner	11:15 – 11:30
Data Management	Anshika Tripathi	11:30 – 12:00
Lunch	All	12:00 - 1:00

AGENDA – DAY 2 AFTERNOON

Investigator Breakout		SC and Pharmacist Breakout		Time
Safety and Risk Management	Rulan Griesel	Lab Management	Morgan Gapara	1:00 -1:30
Investigational Product	Peter Leone	IWRS	Viviana Wilches	1:30 – 2:00
Investigator Videos	Paul Wannamaker	Investigational Product	Peter Leone	2:00 – 2:30
Break		All		2:30 – 2:45
Patient Walkthrough		Viviana Wilches		2:45 – 3:15
Timelines and Next Steps		Christine Nase		3:15 – 3:30
Closing Remarks		Peter Leone & Jan Losos		3:30 – 3:45

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DAY 1 RE-CAP

Paul Wannamaker

Clinical Science Lead

FEEDBACK FROM BREAKOUT SESSIONS

- Staffing shortages may be an issue with a time intensive study visit schedule
- Visit frequency and timing may be a challenge for participants who are working
- Out of hours site support might help if there was Sponsor support
- Important to ensure that participants are aware of the MOA of the N6LS and how it is being evaluated for host immune system engagement
- Prolonged screening period due to phenotypic sensitivity assay turn around times may be an issue – participants don't want to wait that long to get started on something
- Implementation Science is going to be an important component of this study
- Some centers would not be able to support the infusion needs that a commercial IV N6Ls formulation might require
- Where infusion service are not available, subcutaneous infusion is largely preferred as the route of administration
- Can you retest the Monogram Phenosense assay is the first result fails?
- Is someone on Juluca eligible?
- If you see an injection site reaction after the first dose, can you premedicate for the following N6LS infusions?

FEEDBACK FROM BREAKOUT SESSIONS

- Staffing shortages may be an issue with a time intensive study visit schedule
- Special pump for s/c delivery is difficult in the clinic setting

- To be able to adopt N6LS as a product, reimbursement for procedures needs to be worked out
- Most site felt that although the sensitivity assay is problematic, they are more comfortable with having a screening assay than treating all comers

- The age group that will qualify for N6LS is an the older end of the spectrum, but the limit to the number of prior regimens they can be will limit their participation

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PROTOCOL OVERVIEW CON'T

Chelsea Macfarlane

Clinical Science Lead

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Inclusion/Exclusion Criteria

ELIGIBILITY

Re Screening

- Participants are allowed to rescreen for this study one time with the exception of clinically irreversible findings in Screening; examples include but are not limited to:
  - phenotypic sensitivity, liver cirrhosis, CDC Stage 3 disease, drug allergy/sensitivity, significant psychiatric disorder, or cardiac arrythmias.

- Participant must be issued a new participant number

- Initial screen data recorded as a “screen failure” in CRF.

- A single repeat per laboratory test (e.g. creatinine clearance, ALT, is allowed within the Screening Phase with the exception of a Screening plasma HIV > 50 c/ml

- ViiV/GSK will not grant exemptions for eligibility

INCLUSION/EXCLUSION CRITERIA

Key Inclusion Criteria

Age

1) Participant must be 18 to 70 years

2) **Must be on uninterrupted current regimen (either the initial or second ARV regimen) for at least 6 months prior to Screening. Any prior switch, defined as a change of a single drug or multiple drugs simultaneously, must have occurred due to tolerability/safety, access to medications, or convenience/simplification, and must NOT have been done for treatment failure (HIV-1 RNA ≥200 c/mL).**

- Acceptable stable (initial or second) ARV regimens prior to Screening include at least one NRTI plus:
- INI (either the initial or second cART regimen)
- NNRTI (either the initial or second cART regimen)
- Boosted PI (or atazanavir [ATV] unboosted) (must be either the initial cART regimen or one historical within class switch is permitted due to safety/tolerability)
- **Excludes current use of cabotegravir or fostemsavir**

- The addition, removal, or switch of a drug(s) that has been used to treat HIV based on antiretroviral properties of the drug constitutes a change in ART with the following limited exceptions:
  - Historical changes in formulations of ART drugs or booster drugs **will not** constitute a change in ART regimen if the data support similar exposures and efficacy, and the change must have been at least 3 months prior to Screening.
  - Historical maternal perinatal use of an NRTI when given in addition to an ongoing HAART will not be considered a change in ART regimen.
  - A change in dosing scheme of the same drug from twice daily to once daily **will not** be considered a change in ART regimen if data support similar exposures and efficacy.

- **3) Documented evidence of at least two plasma HIV-1 RNA measurements <50 c/mL in the 12 months prior to Screening: one within the 6 to 12-month window, and one within 6 months prior to Screening;**
- **4) Plasma HIV-1 RNA <50 c/mL at Screening;**
- **5) Screening CD4+ T-cell count ≥350 cells/mm^3**: NOTE: A single repeat test is allowed to determine eligibility.
- **6) Body weight ≥50 kg to ≤115 kg.**

INCLUSION/EXCLUSION CRITERIA

Inclusion Criteria:

- 7) Male and/or female

Contraceptive use by men or women should be consistent with local regulations regarding the methods of contraception for those participating in clinical studies, assuring minimal contraception requirements noted below.

All participants participating in the study should be counselled on safer sexual practices including the use and benefit/risk of effective barrier methods (e.g. male condom) and on the risk of HIV transmission to an uninfected partner.

- Participants **who are female at birth** are eligible to participate if at least one of the following conditions applies:
  - Not pregnant or breastfeeding and at least one of the following conditions applies:
    - Is not a participant of childbearing potential (POCBP)
  - OR
    - Is a POCBP and using an acceptable contraceptive method as described in Section 10.4 during the intervention period (at a minimum until after the last dose of study intervention). The investigator should evaluate the effectiveness of the contraceptive method in relationship to the first dose of study intervention.
  - A POCBP must have a negative highly sensitive (see Section 10.4) pregnancy test (urine or serum as required by local regulations) on Day 1, prior to the first dose of study intervention.
  - If a urine test cannot be confirmed as negative (e.g., an ambiguous result), a serum pregnancy test is required. In such cases, the participant must be excluded from participation if the serum pregnancy result is positive.
  - Additional requirements for pregnancy testing during and after study intervention are located in Section 1.3.
  - The investigator is responsible for review of medical history, menstrual history, and recent sexual activity to decrease the risk for inclusion of a POCBP with an early undetected pregnancy.

Contraception Guidance and Collection of Pregnancy Information can be found in Section 10.4

INCLUSION/EXCLUSION CRITERIA

Inclusion Criteria:

- 8) QTc Interval <450 msec.
- **9) Viral phenotypic sensitivity to VH3810109 based on IC_{90} of ≤2 µg/mL and a Maximum Percent Inhibition >98% using the Monogram *PhenoSense* mAb Assay on sample obtained at a screening visit.**
- 10) Capable of giving signed informed consent which includes compliance with the requirements and restrictions listed in the informed consent form (ICF) and in this protocol.

Key Exclusion Criteria

- 1) Participants who are pregnant, breastfeeding, plan to become pregnant or breastfeed during the study.
- **2) The participant has a skin disease or disorder (i.e. infection, inflammation, dermatitis, eczema, drug rash, drug allergy, psoriasis, food allergy, urticaria) or tattoo overlying potential injection sites which may interfere with interpretation of injection site reactions or administration of VH3810109 or CAB.**
- **3) Participant has a gluteal implant/enhancements (including fillers) overlying the gluteus area or any other area which may significantly interfere with interpretation of injection site reactions.**
- **4) Known history of cirrhosis with or without viral hepatitis co-infection.**
- **5) Ongoing or clinically relevant pancreatitis**
- 6) Participants with chronic hepatitis B (HBsAg positive) infection
  - Individuals who are co-infected with HIV and Hepatitis B virus (HBV) will be excluded. Exclusion will be determined by evidence of HBV infection based on the results of testing at Screening for Hepatitis B surface antigen (HBsAg), Hepatitis B core antibody (HBcAb), Hepatitis B surface antibody (HBsAb) and HBV DNA as follows:
    a) Participants positive for HBsAg are excluded;
    b) Participants negative for HBsAb and negative for HBsAg but positive for hepatitis B core antibody (HBcAb) may be excluded based on the following consideration:
      - Exclude if HBV DNA is detected [either < Lower Limit of Quantification (LLoQ), > Upper Limit of Quantification (ULoQ) OR numerical value (i.e., between LLoQ and ULoQ)]
      - Not excluded if HBV DNA is negative, not detected

Note: Participants positive for HBcAb, negative for HBsAg and positive for HBsAb (past and/or current evidence, e.g. at screening) are considered to be immune to HBV and are not excluded.

INCLUSION/EXCLUSION CRITERIA

Exclusion Criteria

7) Participants with Hepatitis C co-infection.

- However, participants with HCV co-infection will be allowed entry into this study if:
- Liver enzymes meet entry criteria;
- HCV Disease has undergone appropriate work-up, and is not advanced, and will not require treatment prior to the primary endpoint (e.g., Month 6) or later visit. Additional information (where available) on participants with HCV co-infection at screening should include results from any liver biopsy, Fibroscan, ultrasound, or other fibrosis evaluation, history of cirrhosis or other decompensated liver disease, prior treatment, and timing/plan for HCV treatment;
  - In the event that recent biopsy or imaging data is not available or inconclusive, the Fib-4 score will be used to verify eligibility
    - Fib-4 score >3.25 is exclusionary
    - Fib-4 scores 1.45 – 3.25 requires Medical Monitor consultation
    - Fibrosis 4 Score Formula: (Age x AST) / (Platelets x (sqr [ALT])

8) Unstable liver disease (as defined by any of the following: presence of ascites, encephalopathy, coagulopathy, hypoalbuminemia, esophageal or gastric varices, or persistent jaundice or cirrhosis), known biliary abnormalities (with the exception of Gilbert's syndrome or asymptomatic gallstones or otherwise stable chronic liver disease per investigator assessment).

9) Untreated syphilis infection (positive rapid plasma reagin (RPR) at screening) without documentation of treatment. Participants who are at least 7 days post completed treatment are eligible if recruitment is open. Rescreening is allowed after treatment.

10) Prior receipt of licensed or investigational HIV monoclonal antibody.

11) Any evidence of an active Centers for Disease Control and Prevention (CDC) Stage 3 disease [CDC, 2014], except cutaneous Kaposi's sarcoma not requiring systemic therapy. Historical or current CD4 cell counts less than 200 cells/mm^3 are not exclusionary.

INCLUSION/EXCLUSION CRITERIA

Exclusion Criteria

12) **Participants determined by the Investigator to have a high risk of seizures, including participants with an unstable or poorly controlled seizure disorder**. A participant with a prior history of seizure may be considered for enrolment if the Investigator believes the risk of seizure recurrence is low. All cases of prior seizure history should be discussed with the Medical Monitor prior to enrolment.

13) Clinically significant cardiovascular disease, as defined by history/evidence of congestive heart failure, symptomatic arrhythmia, angina/ischemia, coronary artery bypass grafting (CABG) surgery or percutaneous transluminal coronary angioplasty (PTCA), atherosclerotic cardiovascular disease (ASCVD) risk score of ≥20%, or any cardiac disease deemed clinically significant at the discretion of the investigator.

14) Ongoing malignancy other than cutaneous Kaposi's sarcoma, basal cell carcinoma, or resected, non-invasive cutaneous squamous cell carcinoma, or cervical, anal or penile intraepithelial neoplasia; other localized malignancies require agreement between the investigator and the study medical monitor for inclusion of the participant prior to randomization.

15) Any pre-existing physical or mental condition which, in the opinion of the investigator, may interfere with the participant's ability to comply with the dosing schedule and/or protocol evaluations, or which may compromise the safety of the participant.

16) Participants with substance abuse disorders or social restraints that the investigator considers to be possible deterrents to successful completion of the study.

17)Participants who in the investigator's judgment, pose a significant suicidality risk. Participants' history of suicidal behavior and/or suicidal ideation should be considered when evaluating for suicide risk.

INCLUSION/EXCLUSION CRITERIA

Exclusion Criteria

18) History of sensitivity to any of the study medications or their components or drugs of their class, or a history of drug or other allergy that, in the opinion of the investigator or Medical Monitor, contraindicates their participation.

19) Any condition which, in the opinion of the investigator, may interfere with the absorption, distribution, metabolism or excretion of the study drugs, cART or render the participant unable to take oral medication.

20) Participants with a positive COVID-19 test at Screening. Participants with known COVID-19 positive contacts within the past 14 days, or with symptoms suggestive of active COVID-19 (fever, cough, myalgias, shortness of breath, loss of taste or smell), should be excluded. Participants who remain symptom-free for at least 14 days after a COVID-19 exposure are allowed.

21) Contraindications, as per the current Prescribing Information for cabotegravir.

- **Previous hypersensitivity reaction to cabotegravir or**
- **Contraindicated co-administered drugs:**
  - **Anticonvulsants: Carbamazepine, oxcarbazepine, phenobarbital, phenytoin**
  - **Antimycobacterials: Rifabutin, rifampin, rifapentine**
  - **Glucocorticoid (systemic): Dexamethasone (more than a single-dose treatment)**
  - **Herbal product: St John's wort (Hypericum perforatum)**

INCLUSION/EXCLUSION CRITERIA

Other Exclusion Criteria

Prior/Concomitant Therapy

22) Treatment with an HIV-1 immunotherapeutic vaccine within 90 days of Screening.

23) Previous exposure to cabotegravir.

24)Treatment with any of the following agents within 60 days of screening:

- **radiation therapy;**
- **cytotoxic chemotherapeutic agents;**
- **any systemic immune suppressant;**

25) Exposure to an experimental drug or experimental vaccine within either 28 days, 5 half-lives of the test agent, or twice the duration of the biological effect of the test agent, whichever is longer, prior to the first dose of study medication.

26) Current or anticipated need for chronic anti-coagulants.

27) Participants receiving any prohibited medication and who are unwilling or unable to switch to an alternate medication.

INCLUSION/EXCLUSION

Other Exclusion Criteria

28) Participant enrolled in a prior or concurrent clinical study that includes a drug intervention within the last 30 days.

Diagnostic Assessments

29) Any acute laboratory abnormality at Screening, which, in the opinion of the investigator, would preclude the participant's inclusion in the study of an investigational compound.

30) Any evidence of viral resistance based on the presence of any major cabotegravir resistance-associated mutation [IAS-USA, 2022] in any historic resistance test result.

31) Any verified Grade 4 laboratory abnormality with the exception of Grade 4 triglycerides or lipid abnormalities. A single repeat test is allowed during the Screening period to verify a result.

32) Alanine aminotransferase (ALT) ≥3 times the upper limit of normal (ULN)

33) Creatinine clearance of <50 mL/min/1.73 m^2 via using the refitted, race-neutral Chronic Kidney Disease Epidemiology Collaboration (CKD-EPIcr_R) method.

34) PT ≥ Grade 2 (1.25 ≥ ULN). A single repeat test is allowed during the Screening period to verify a result.

INCLUSION/EXCLUSION CRITERIA

Other Important Exclusion Criteria

To assess any potential impact on participant eligibility with regard to safety, the investigator must refer to the IB and supplements, approved product labels, and/or local prescribing information for detailed information regarding warnings, precautions, contraindications, AEs, drug interactions, and other significant data pertaining to the study drugs.

CD [male, 54 years old] is interested in participating in the EMBRACE Study. He was diagnosed with HIV 15 years ago. He is currently taking DTG/abacavir/3TC, after switching from TDF/FTC/EFV a few months ago. His last CD4 count was 420 and he is virally suppressed. His laboratory results are all within normal ranges.
Are there any actions the site need to take?

Yes- CD appears to be eligible pending screening results
No- CD does not appear to meet eligibility requirements
I am not sure- I would like to get more information.

Polling Discussion

Need to confirm CD has been on DTG/Abacavir/3TC for least 6 months

Need to confirm that the switch from TDF/FTC/EFV was not due to Virologic Failure

Yes- CD appears to be eligible pending screening results

No- CD does not appear to meet eligibility requirements

I am not sure- I would like to get more information.

AB is a 27 yo female PWH who initiated HAART with Truvada/ EFV for 2 years, then switched to Descovy+DRV/cobicstat for tolerability and then switched to Symtuza for simplification 4 months prior to screening. Is AB eligible for EMBRACE?

Yes- AB appears to be eligible pending screening results
No- AB does not appear to meet eligibility requirements
I am not sure- I would like to get more information

Polling Discussion

Need to be on stable ART for six months- AB was on multiple single ARVs and changed to a combined formulation of the same single compounds (allowed per protocol)

A change of formulation is not considered a change in regimen.

Yes- AB appears to be eligible pending screening results

No- AB does not appear to meet eligibility requirements

I am not sure- I would like to get more information.

RG is a 21 yo male PWH.
He was diagnosed with primary syphilis at Screening and was treated with a single injection of long acting Benzathine 10 days post-screening, is RG eligible if meeting all other entry criteria?

Yes- RG appears to be eligible pending screening results
No- RG does not appear to meet eligibility requirements
I am not sure- I would like to get more information

Polling Discussion

A single injection of long-acting Benzathine penicillin G can cure the early stages of syphilis. This includes primary, secondary, or early latent syphilis.

RG, if he met all other eligibility criteria would be eligible

- Yes- RG appears to be eligible pending screening results
- No- RG does not appear to meet eligibility requirements
- I am not sure- I would like to get more information.

MC is a 34 yo female PWH.
She was diagnosed with Rheumatoid Arthritis 12 months ago and is being treated with methotrexate injections. Is she eligible?

Yes- MC appears to be eligible pending screening results
No- RG does not appear to meet eligibility requirements
I am not sure- I would like to get more information

Polling Discussion

Having an autoimmune condition is not an exclusion criteria

Taking systemic immunosuppressants within 60 days of the study is exclusionary

Yes- MC appears to be eligible pending screening results

No- MC does not appear to meet eligibility requirements

I am not sure- I would like to get more information.

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Schedule of Assessments

Table 1 Schedule of Activities

Schedule of Activities- Participants randomized to VH[illegible]9 IV Q4M + CAB IM QM

Procedures VH3810109 IV Q4M + CAB IM QM	Screening (up to 75 days before Day 1)	Intervention Period: Day 1 Baseline	Week 1	Week 2	Month 1	Month 1 + 2 weeks	Month 2, 3	Months 4, 5	Month 6	Months 8, 12	Months 7, 9, 11, 13, 15, 17, 19, 21, 23	Months 10, 14, 18, 22	Months 16, 20	Month 24	Continued Access Phase: Every month following Month 24	Early Discontinuation/ Withdrawal	Long-term FU (3, 6, 9, 12 mos. following discontinuation)
Clinical and Other Assessments																	
Informed consent	X																
Eligibility verification	X	X															
Demography[1]	X																
Prior ARV history	X																
Medical history	X																
CV risk assessment	X																
Height, weight (W) and BMI	X	X							X	X				X		X	
Vital signs	X	X							X	X				X		X	
Physical exam (F=Full, T=Targeted)	F	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T

Schedule of Activities- Participants randomized to VH3810109 + rHuPH20 SC Q4M + CAB IM QM

Final Protocol

Procedures VH3810109 + rHuPH20 SC Q4M + CAB IM QM	Screening (up to 75 days before Day 1)	Intervention Period: Day 1 Baseline	Week 1	Week 2	Month 1	Month 1 + 2 weeks	Month 2, 3	Months 4, 5	Month 6	Months 8, 12	Months 7, 9, 11, 13, 15, 17, 19, 21, 23	Months 10, 14, 18, 22	Months 16, 20	Month 24	Continued Access Phase: Every month following Month 24	Early Discontinuation/ Withdrawal	Long-term FU (3, 6, 9, 12 mos. following discontinuation)
Clinical and Other Assessments																	
Informed consent	X																
Eligibility verification	X	X															
Demography[1]	X																
Prior ARV history	X																
Medical history	X																
CV risk assessment	X																
Height, weight (W) and BMI	X	X							X	X				X		X	
Vital signs	X	X							X	X				X		X	
Physical exam (F=Full, T=Targeted)	F	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
CDC HIV-1 Classification	X	X															
HIV-associated conditions	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Concomitant Medications	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Adverse event (AE)/ SAE assessments	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Schedule of Assessments- Participants randomized to continue Standard of Care

Procedures Standard of Care	Screening (up to 75 days before Day 1)	Intervention Period: Day 1 Baseline	Week 1	Week 2	Month 1	Month 1 + 2 weeks	Month 2, 3	Months 4, 5	Month 6	Months 8, 12	Months 7, 9, 11, 13, 15, 17, 19, 21, 23	Months 10, 14, 18, 22	Months 16, 20	Month 24	Early Discontinuation/ Withdrawal
Informed consent	X														
Eligibility verification	X	X													
Demography[1]	X														
Prior ARV history	X														
Medical history	X														
CV risk assessment	X														
Height, weight (W) and BMI	X	X							X	X				X	X
Vital signs	X	X							X	X				X	X
Physical exam (F=Full, T=Targeted)	F	T	T	T	T	T	T	T	T	T	T	T	T	T	T
CDC HIV-1 Classification	X	X													

All laboratory draws should occur through the Central Lab: Q2 solutions. If a Local Lab test is required, it is important that a Central Lab test is also drawn.

If an alert of suspected virologic failure is received, what should the site do?

a. The patient should be discontinued from the trial

b. A re-test should be performed at least 2 weeks but no more than 4 weeks apart from the original sample, unless a delay is indicated

c. The investigator to contact the study medical monitor.

If an alert of suspected virologic failure is received, what should the site do?

The correct answer is B.
A re-test should be performed at least 2 weeks but no more than 4 weeks apart from the original sample, unless a delay is indicated.

a. The patient should be discontinued from the trial

b. A re-test should be performed at least 2 weeks but no more than 4 weeks apart from the original sample, unless a delay is indicated

c. The investigator to contact the study medical monitor.

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POTENTIAL BENEFITS OF N6LS TREATMENT BEYOND ANTIVIRAL ACTIVITIES

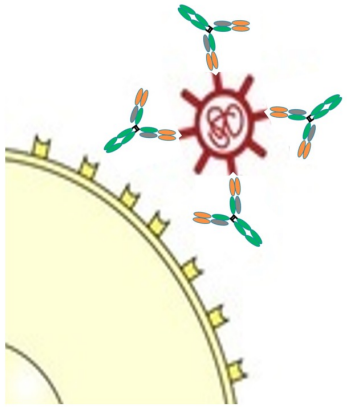
Elizabeth R. Wonderlich

Scientific Leader of

Clinical and Translational Immunology

BNABS POSE "MULTIPLE THREATS" TO HIV

Neutralization
(Direct acting antiviral)



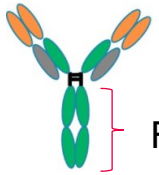
Bind to surface proteins/ glycans on HIV and prevent virus entry into target cells

Neutralization Potency

	N6	VRC27	VRC01	3BNC 117	PG9	PGDM 1400	PGT 121	10-1074	10E8	4E10	35O22
No. of viruses	181	175	177	181	177	171	177	178	180	181	181
IC_{50}<50 µg/ml	98%	78%	89%	83%	78%	78%	64%	66%	98%	98%	62%
IC_{50} <1 µg/ml	96%	56%	73%	76%	64%	70%	50%	60%	72%	37%	48%
GM IC_{50}*	0.044	0.297	0.250	0.094	0.109	0.015	0.051	0.036	0.222	1.303	0.058
Median IC_{50}	0.038	0.217	0.248	0.073	0.088	0.008	0.022	0.022	0.352	1.920	0.033
Binding site		CD4-binding site			V1V2		V3		gp41 MPER		gp120-gp41

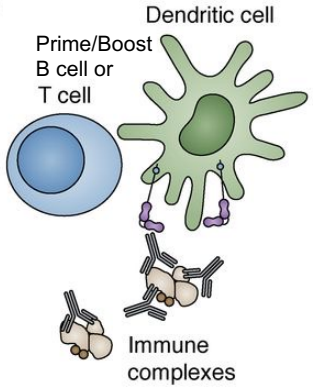
* Geometric Mean IC_{50} concentration is µg/ml.

Enhanced Host Immune Response



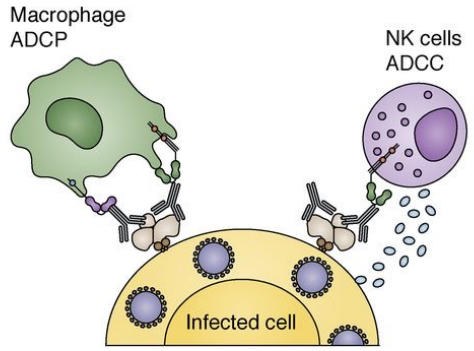
Antigen binding

Fc region binds to Fc Receptors on innate cells

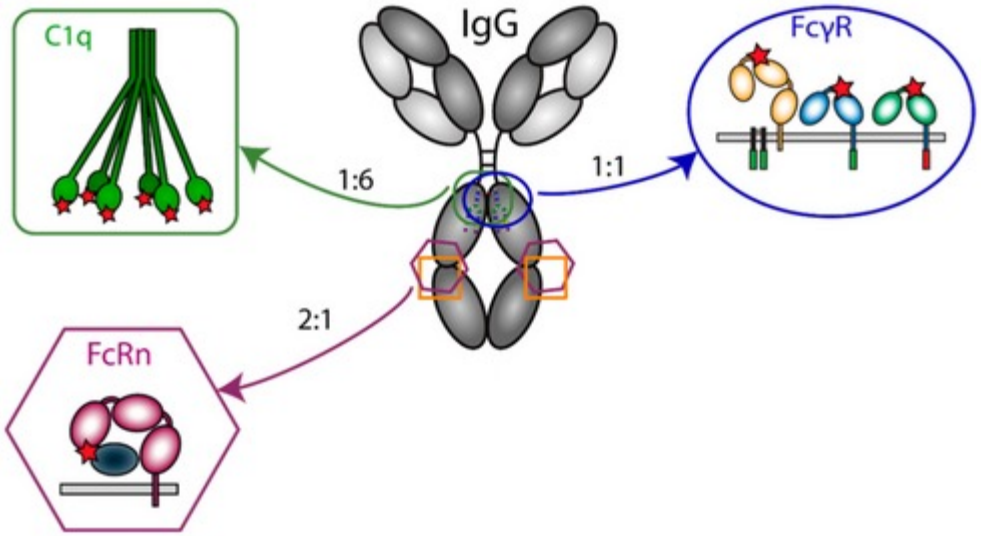


bNAb+virus can form complexes that are presented to the host immune system and may induce:
~ Antibody responses
~ T cell responses

bNAbs can facilitate clearance of infected cells



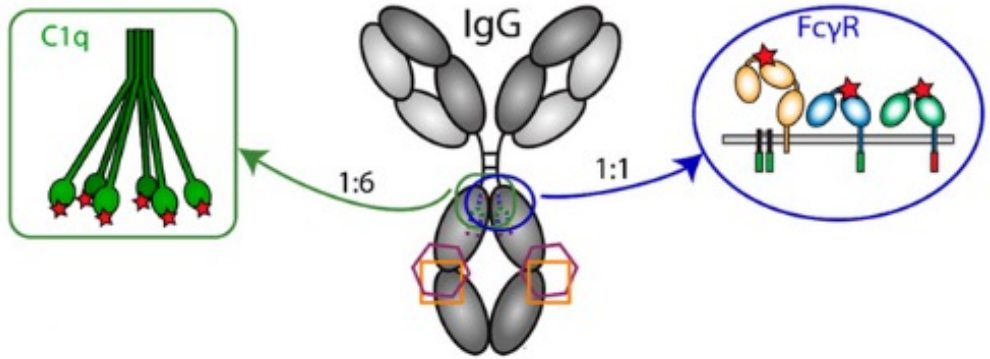
Potential Fc-related activities of n6ls



Region responsible for endosomal recycling

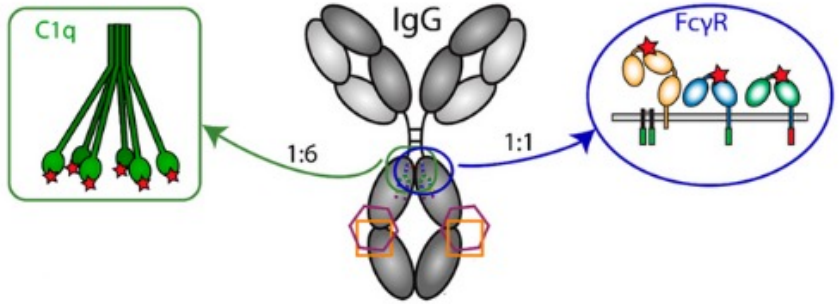
PMID: 31544836

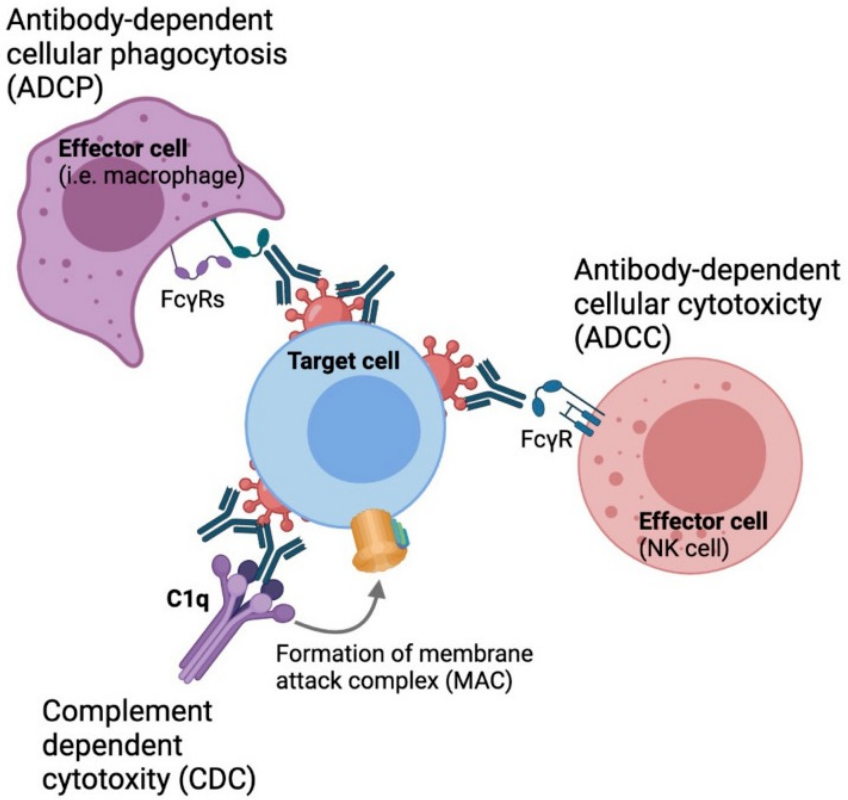
Potential Fc-related activities of n6ls



PMID: 31544836

Potential Fc-related activities of n6ls





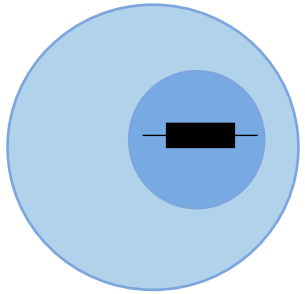
Does N6LS specifically target the HIV reservoir?

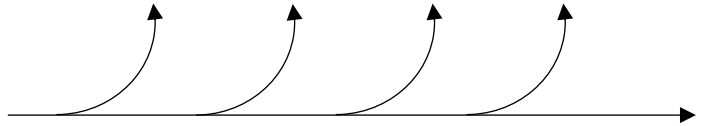
Does N6LS cause a 'vaccinal effect' that increases anti-HIV responses?

PMIDs: 31544836, 34603314

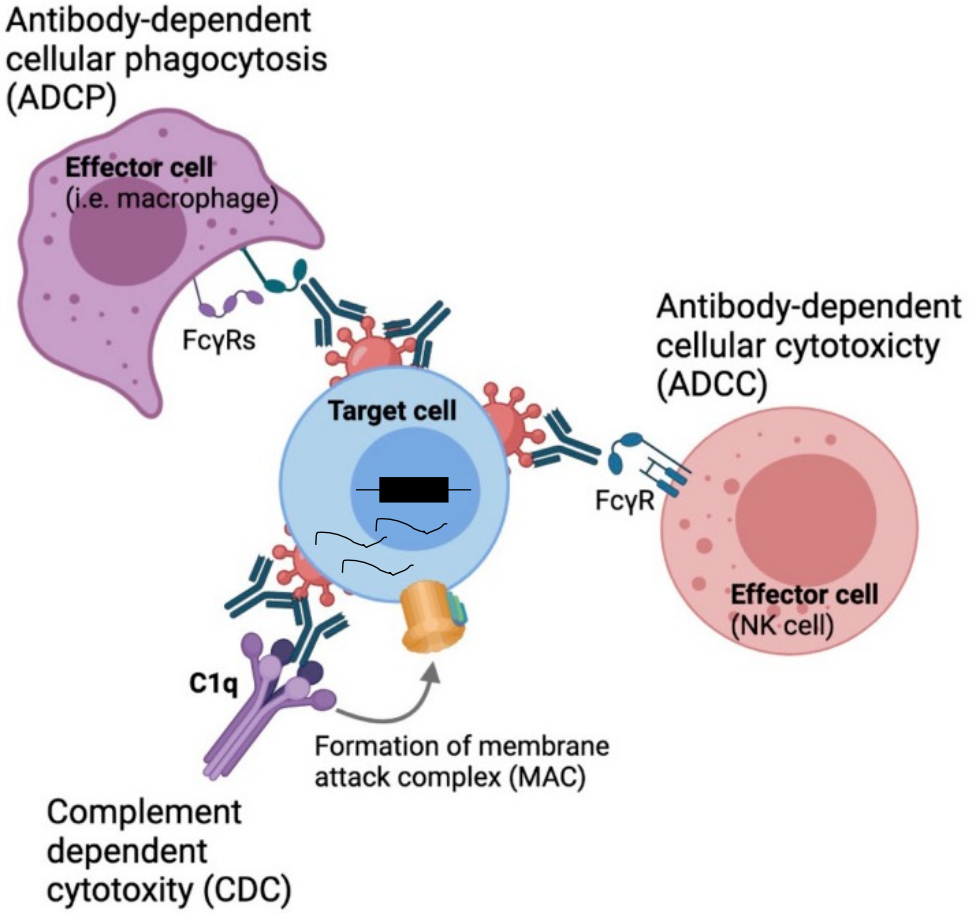
As ThE HIV Reservoir reactivates, Cellular targets of N6ls are created

HIV Reservoir



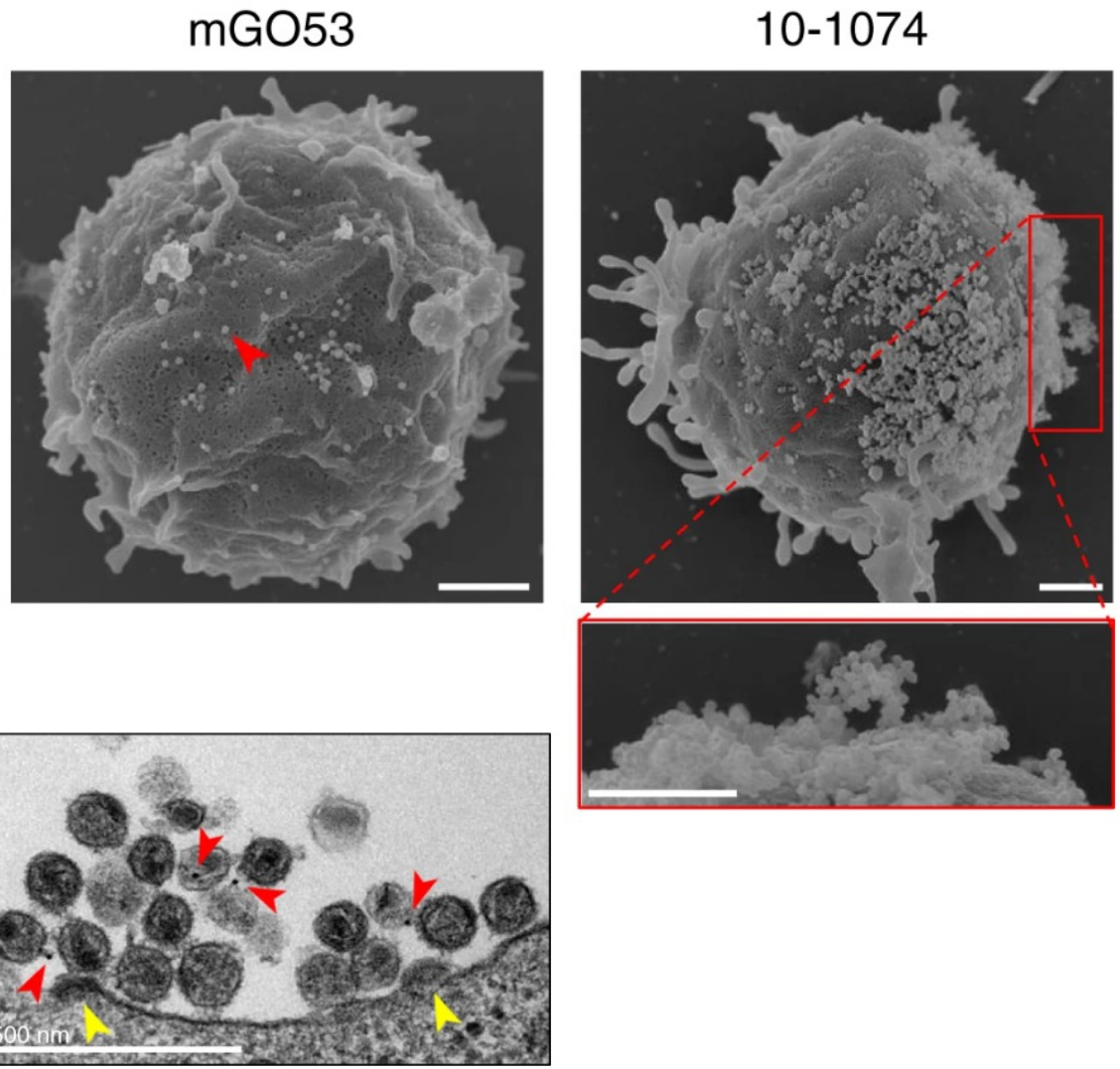


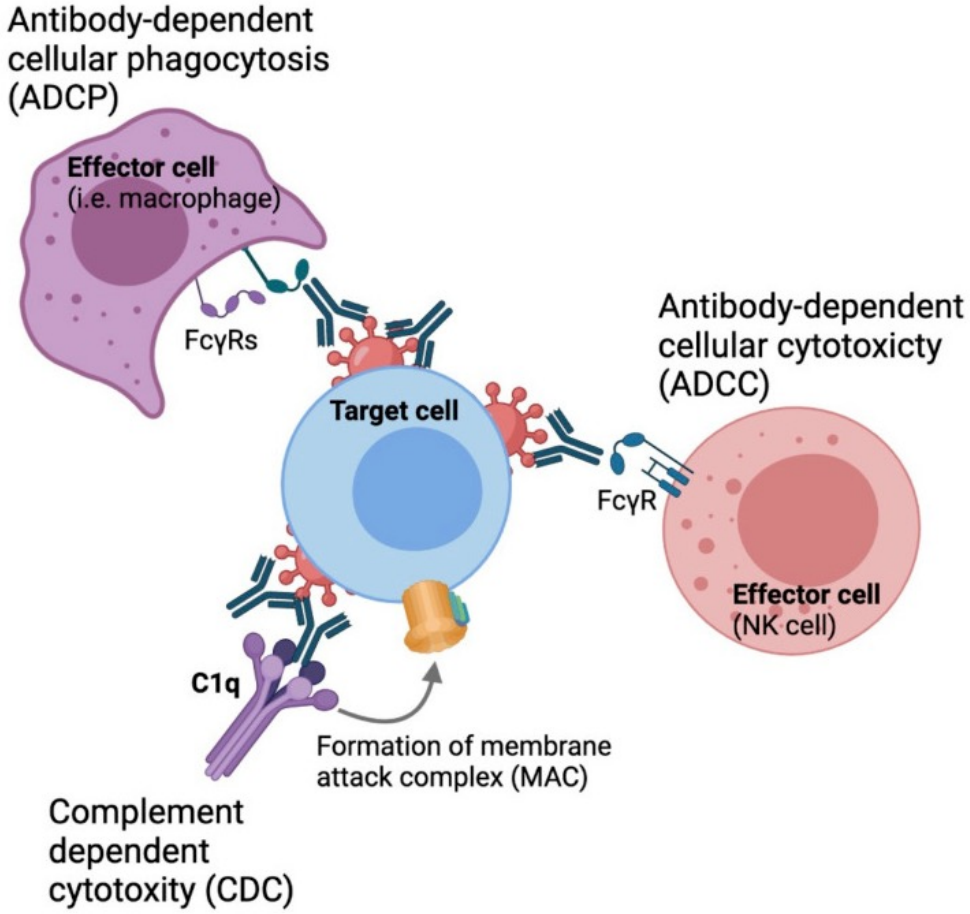
Reactivates every 5-8 days



PMID: 34603314

As the reservoir reactivates, HIV-producing cells may be marked for death

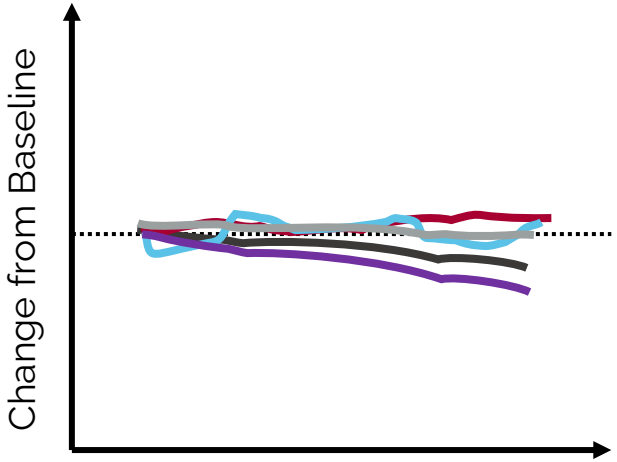




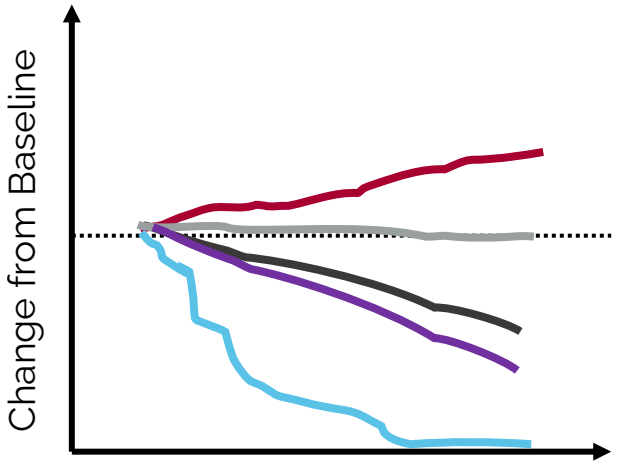
PMID: 35110562, 34603314

N6LS may selectively target cells with active reservoirs

Anticipated Reservoir Kinetics with SOC



Conceivable Reservoir Kinetics with Long-term N6LS Administration



Env-Defective Provirus

Total Provirus

Intact Provirus
QVOA IUPM

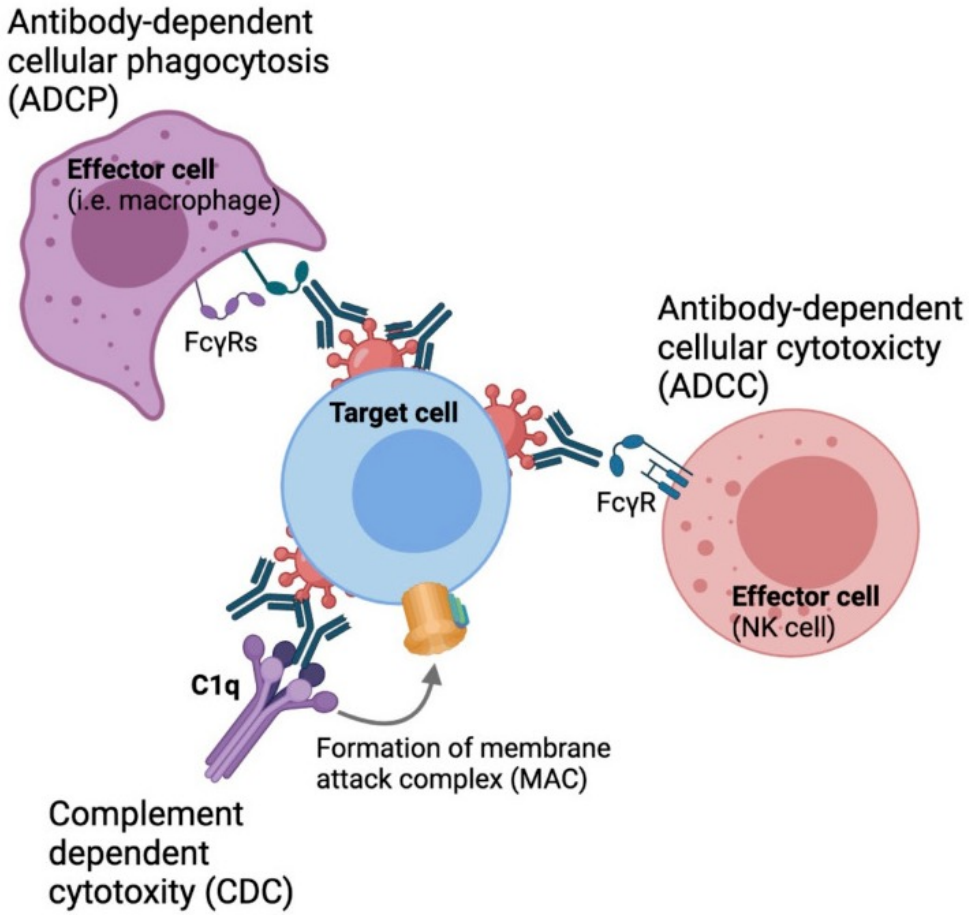
Cell Associated HIV-RNA Transcripts

Theoretical Time in PLWH who have Undetectable Viremia

Laboratory Assessments	Day 1 (baseline)	Week 2	Month 1	Month 2	Month 4	Month 6	Month 8	Month 10	Month 12	Month 16	Month 20	Month 24
PBMC: Total vs Intact provirus	X								X			X
PBMC: Proviral activity (CA-HIV-RNA)	X	X			X				X			X

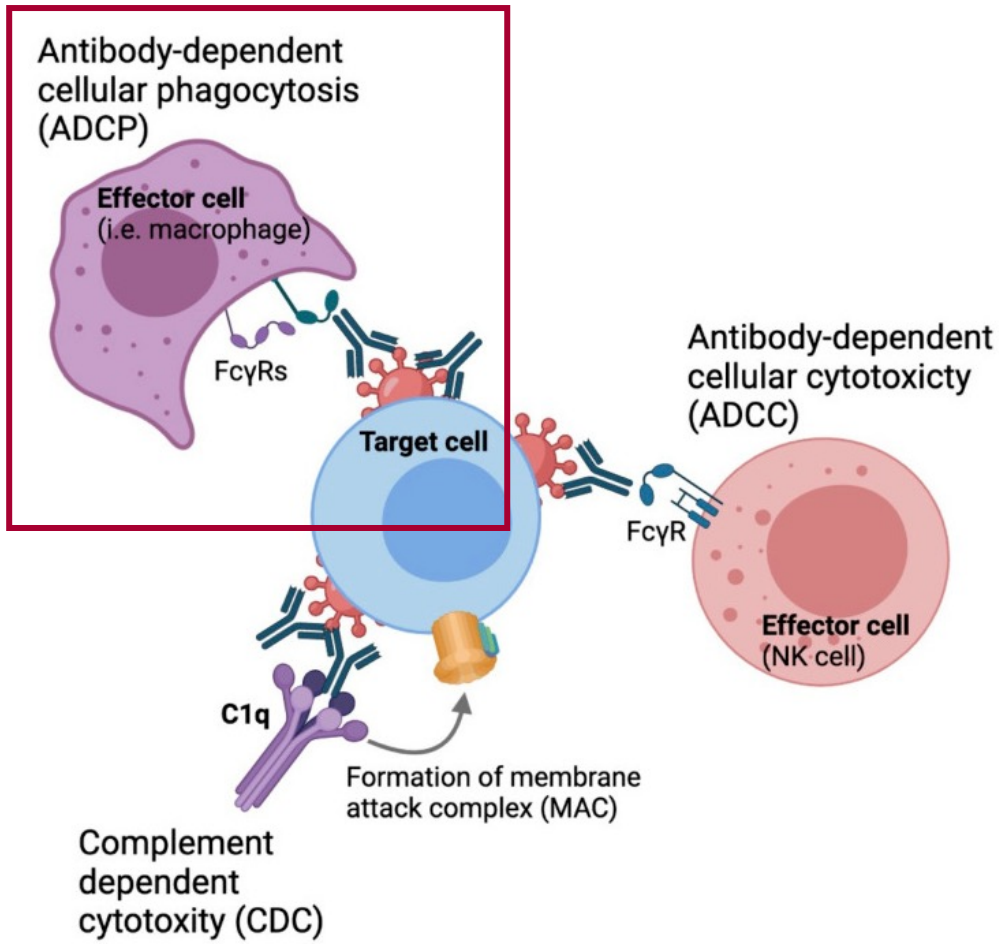
To determine if changes over time are specific to N6LS treatment, all aims will be assessed as changes from baseline and **relative to the SOC treatment arm**.

Potential Fc-related Activities of n6ls



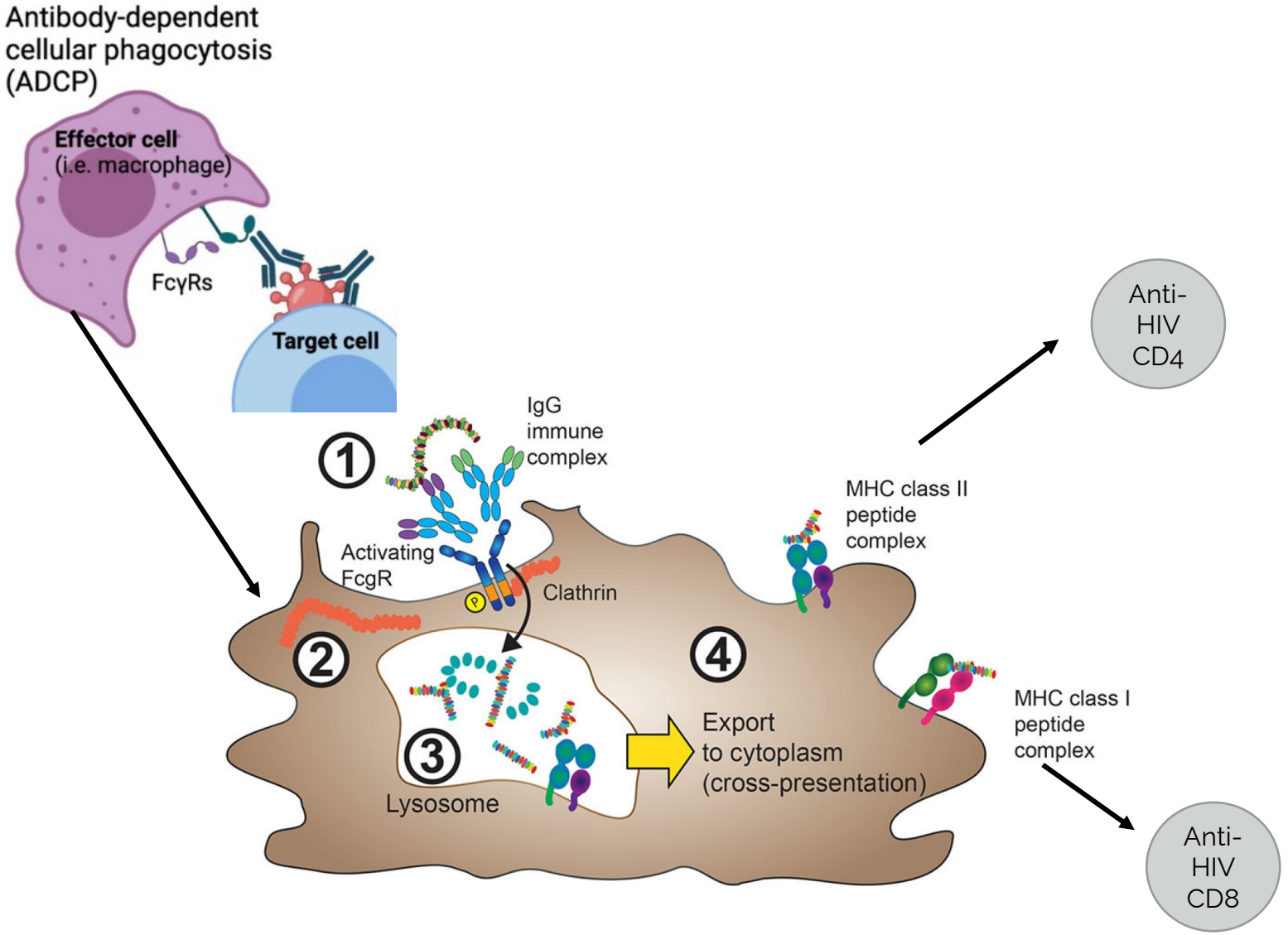
PMID: 34603314

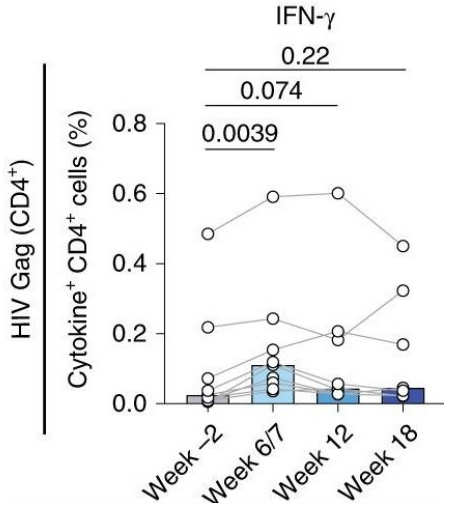
Potential Fc-related Activities of n6ls

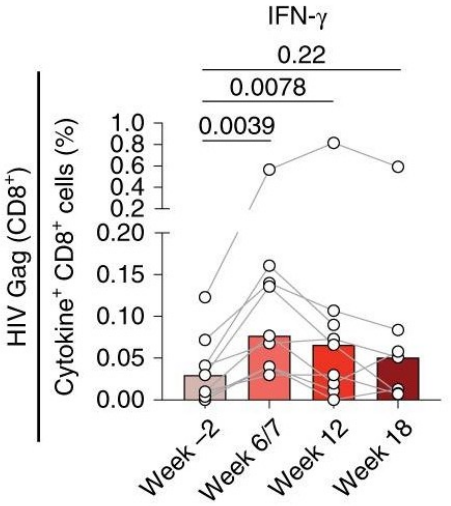


PMID: 34603314

Neutralization and subsequent Immune Complex formation by N6LS may boost anti-hiv immune responses

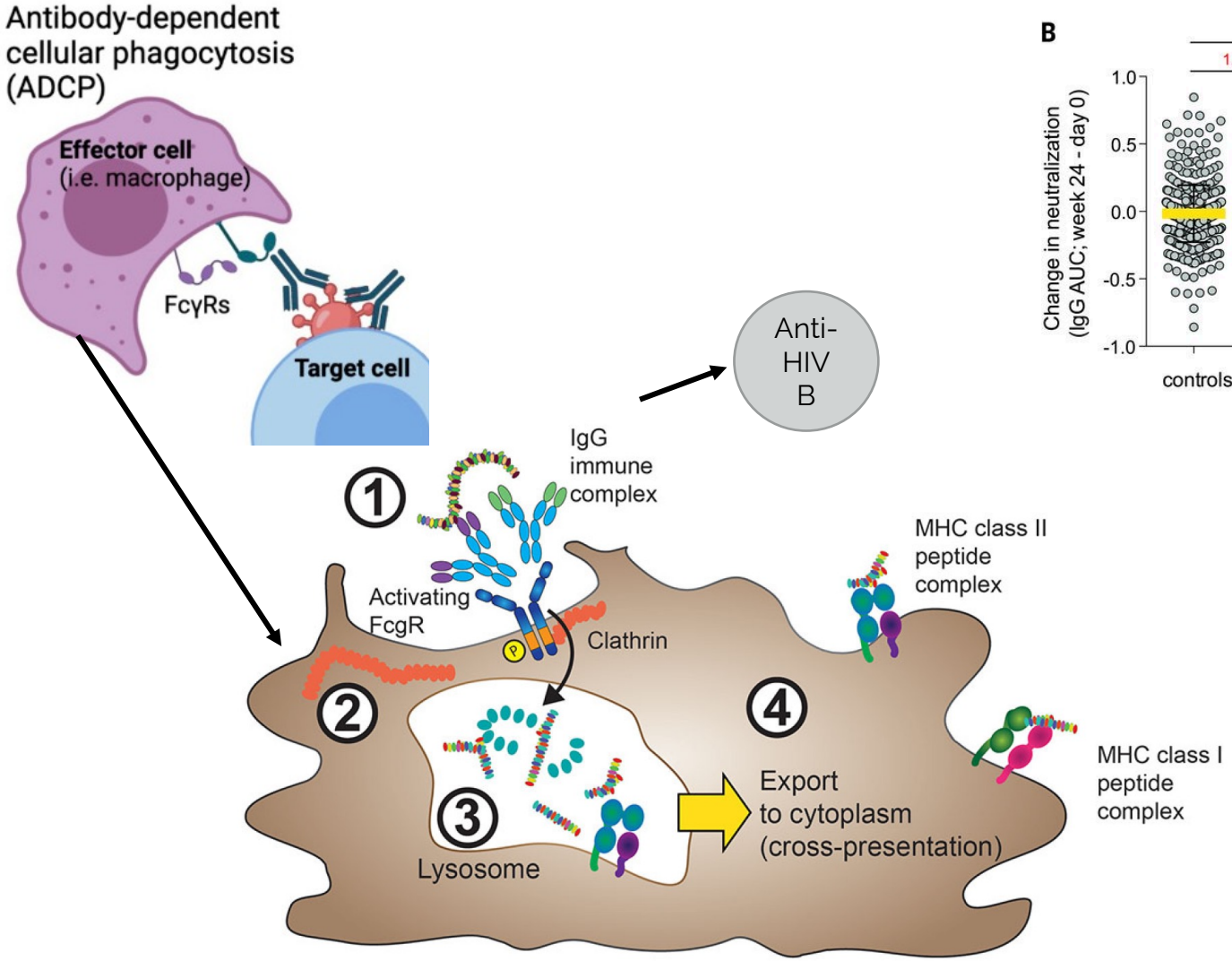


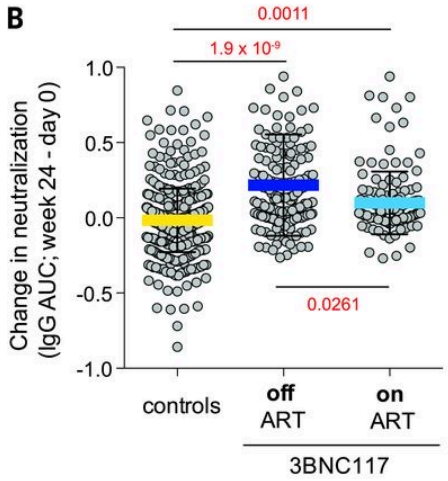


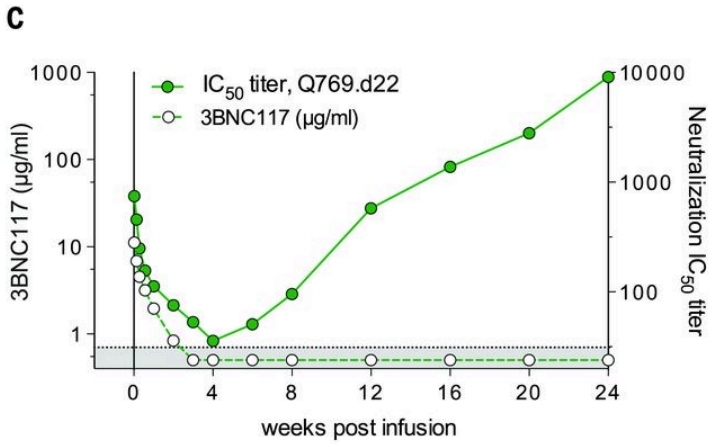


PMIDs: 34603314, 32719679, 32015556

Neutralization and subsequent Immune Complex formation by N6LS may boost anti-hiv immune responses







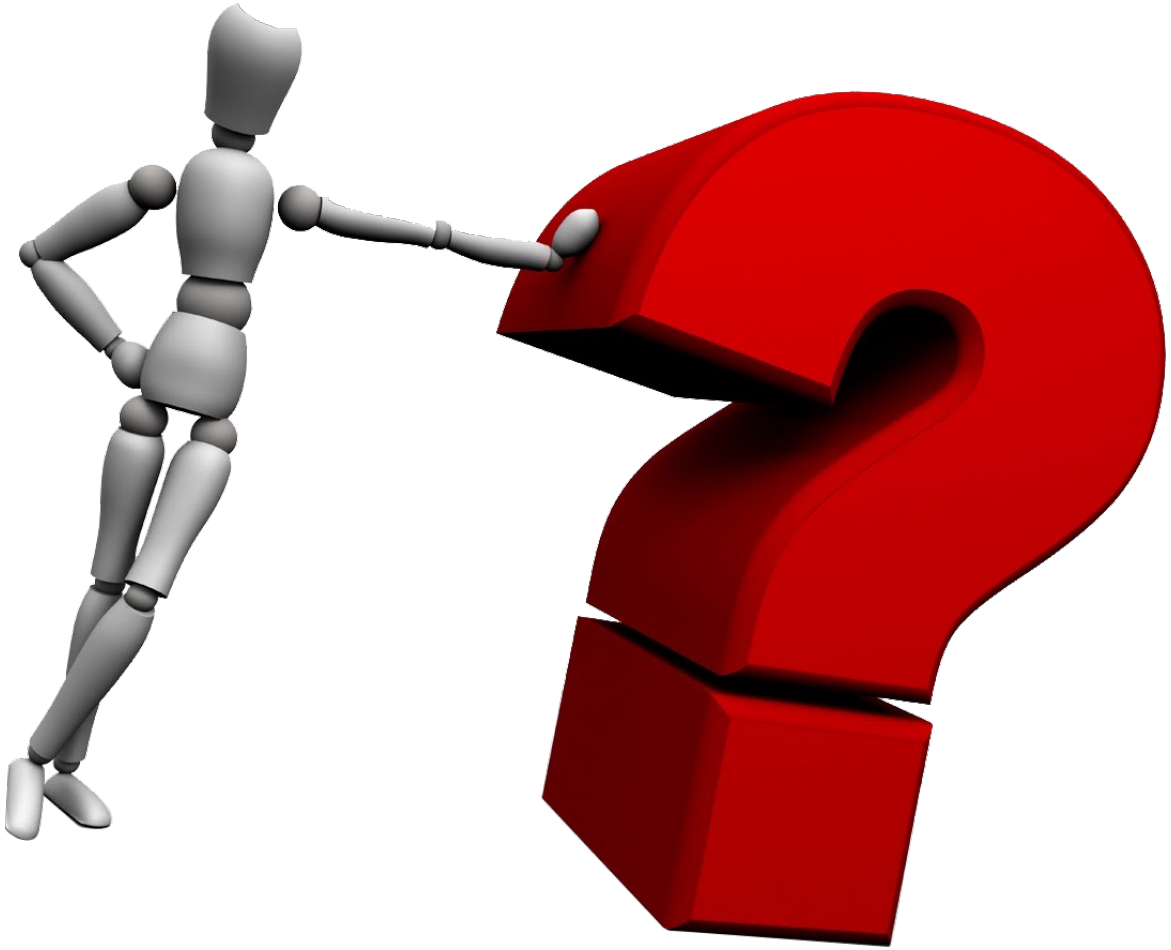
PMIDs: 34603314, 32719679, 27199429

N6LS may specifically enhance autologous anti-hiv immune responses

Laboratory Assessments	Day 1 (baseline)	Week 2	Month 1	Month 2	Month 4	Month 6	Month 8	Month 10	Month 12	Month 16	Month 20	Month 24
PBMC: Anti-HIV T cell Responses	X		X						X			X
Plasma: Autologous Env Neutralization	X								X			

To determine if changes over time are specific to N6LS treatment,
all aims will be assessed as changes from baseline and **relative to the SOC treatment arm**.

Questions?



GSK × ViiV Healthcare

embrace

BREAK

GSK × ViiV Healthcare

embrace

SITE ECOA TRAINING

An Overview of the IQVIA Web Portal eCOA Platform, Subject Creation, and Data Reports

McKenzie Grimes IQVIA eCOA Project Manager

STUDY OVERVIEW – IQVIA ECOA WEB PORTAL AND SCRIBE

The Web Portal

Web Portal for the Site

In the Web Portal, studies are managed, subjects are created, and responses are collected.

Two Tools, One Process

The Scribe App

Response Platform for the subject and clinician

In Scribe, assessments are presented to the subject and clinician in the form of eDiaries, and responses are collected.

STUDY EDIARY OVERVIEW – AT A GLANCE

+ During the screening visit subjects **must** read and accept GSK privacy policy within the eDiary app, prior to complete their training module and accessing the study questionnaires

+ During the subjects scheduled visit, site staff must activate the visits within the app for the subject to access their visit assessment, It is mandatory to instruct the subject to bring their device to ALL site visits throughout the duration of the study

+ Subjects enrolled to the **VH3810109 IV Q4M + CAB IM QM** and **VH3810109 + rHuPH20 SC Q4M + CAB IM QM** treatment arms
  - **Site staff must ensure subject completes the following questionnaire BEFORE to receiving their injection/infusion**
    - Acceptance Questionnaire (ACCEPT)
    - HIV Treatment Satisfaction Questionnaire (HIVTSQ)
    - EuroQol (EQ-5D-3L)
  - **Site staff must ensure subjects complete the following questionnaire AFTER receiving their injection/infusion**
    - PIN (Perception of Injection)
    - Injection Site Pain Numeric Rating Scale
    - Implementation Science Questionnaire
    - ISR diary card (completed in the evening after treatment)

STUDY OVERVIEW – LIST OF TASKS

Site Tasks

- ❑ Request the creation of the subject profile in the Web Portal by contacting e-COA Customer Care Team
- ❑ Assist subject with download of Scribe App and ensure subject understanding as they complete their Training Diary
- ❑ Activate subject visit assessment
- ❑ Monitor subject eDiary responses and compliance in the Web Portal
- ❑ Complete C-SSRS

Subject Tasks

- ❑ Download the IQVIA Scribe App on their device for completion of questionnaire (Ecoa)
  - ❑ Subject provided with provisioned device will have the app pre-installed
- ❑ Read and Acknowledge the GSK privacy policy within the eDiary App
- ❑ Complete their Training Diary during Screening
- ❑ Complete questionnaires according to the study schedule

STUDY OVERVIEW – SUPPLIES FOR SITE AND SUBJECT

Site Supplies

- ❑ **Samsung T505 tablet**
  - ❑ **Case and screen protector**
  - ❑ **Device label**
  - ❑ **USB power cord and adapter**
  - ❑ **WiFi and cellular network enabled**
- ❑ **Access to the IQVIA web portal**
- ❑ **eCOA Site Manual**

Subject Supplies

- ❑ **Provisioned iPhone 8 device** for subject eDiary completion if they cannot use their own phone
  - ❑ **Scribe App pre-installed**
  - ❑ **Credentials provided**
  - ❑ **Wi-Fi access, SIM card, charging cord**
- ❑ **eCOA Participant Manual**

STUDY OVERVIEW – SUBJECT SCHEDULE OF E-DIARY ACTIVITIES

For both treatment arms: VH3810109 IV Q4M + CAB IM QM
VH3810109 + rHuPH20 SC Q4M + CAB IM QM

Assessment	Screening	Intervention Period							
		Day 1 Baseline	Week 1	Month 4	Month 6	Month 8	Months 12	Month 24	Early discontinuation/ Withdrawal
ACCEPT*		X		X	X	X	X	X	X
HIVTSQs*		X			X			X	X
HIVTSQc*					X				X
EQ-5D-3L*		X			X			X	X
PIN**		X			X	X	X	X	X
Injection Site Pain Numeric Scale**		X		X		X	X	X	X
Inject Site Reaction Diary Card - To be completed duration of 14 days**		X		X					
Implementation Science Questionnaire**			X		X			X	

*Subject to complete the questionnaire BEFORE receiving their injection or Infusion
**Subject to complete the questionnaire AFTER receiving their injection or Infusion
~~**Injection Site Reaction Diary Card** – is a daily diary subject must complete at home for a duration of 14 days~~

STUDY OVERVIEW – SUBJECT SCHEDULE OF E-DIARY ACTIVITIES

Standard of Care

Assessment	Screening	Intervention Period							
		Day 1 Baseline	Week 1	Month 4	Month 6	Month 8	Months 12	Month 24	Early discontinuation/ Withdrawal
ACCEPT		X		X	X	X	X	X	X
HIVTSQs		X			X			X	X
HIVTSQc					X				X
EQ-5D-3L					X			X	X

STUDY OVERVIEW – SITE SCHEDULE OF E-DIARY ACTIVITIES

Assessment	Screening	Intervention Period											
		Day 1 Baseline	Week 1	Month 1	Month 2 + 3	Month 4	Months 6	Month 8 +12	Months 5, 7, 9, 10, 11, 13, 14, 15, 17, 18, 19	Months 16, 20	Months 21, 22, 23	Month 24	Early discontinuation/ Withdrawal
C-SSRS Screening/Baseline	X												
C-SSRS Since Last Visit		X	X	X	X	X	X	X	X	X	X	X	X

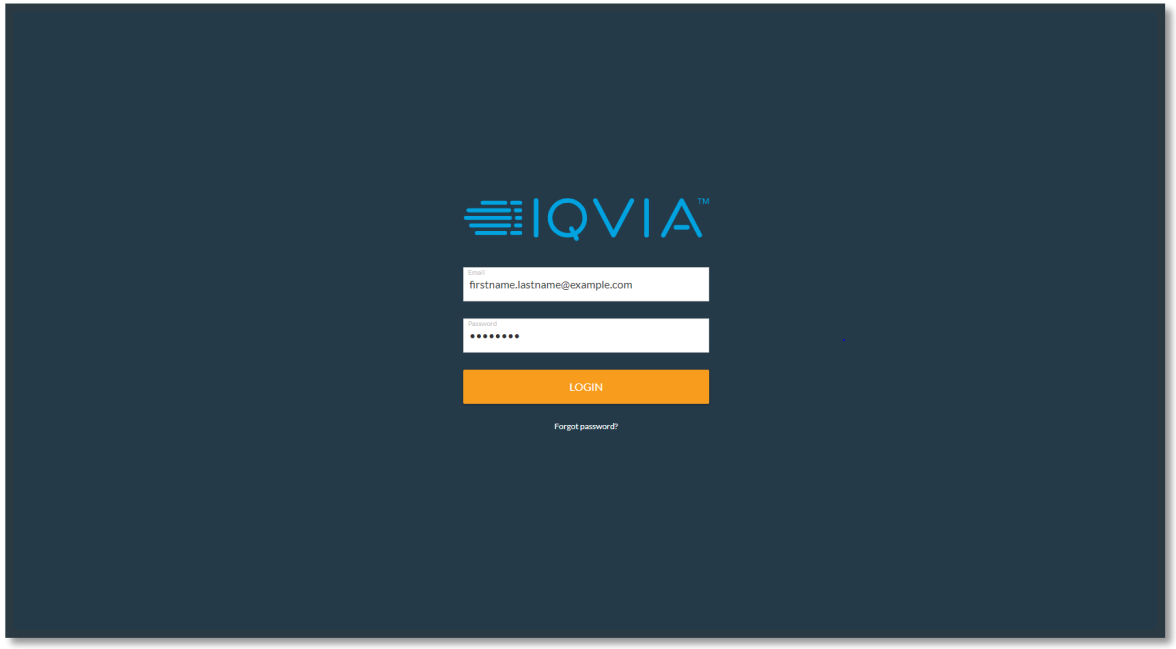
Accessing the Web Portal – Site User

Template No.: ECT_TP_TR0003 Revision 4
Effective Date: 02Jun2023

Reference: ECT_WI_TR0004

THE WEB PORTAL – LOGGING IN

+ Only Site staff, CRAs & Sponsors should access the Web Portal.
+ Log-in Credentials will be provided by the IQVIA study team following your training.
+ Log into mystudy.altavozclinical.com and follow the instructions to reset your password.



THE WEB PORTAL – LOGGING IN AS A SITE USER

IQVIA Creates your Account

- This presentation is the training for using the IQVIA eCOA Web Portal for this study.
- Your site user account will be requested by the project team.

Receive Temporary Password

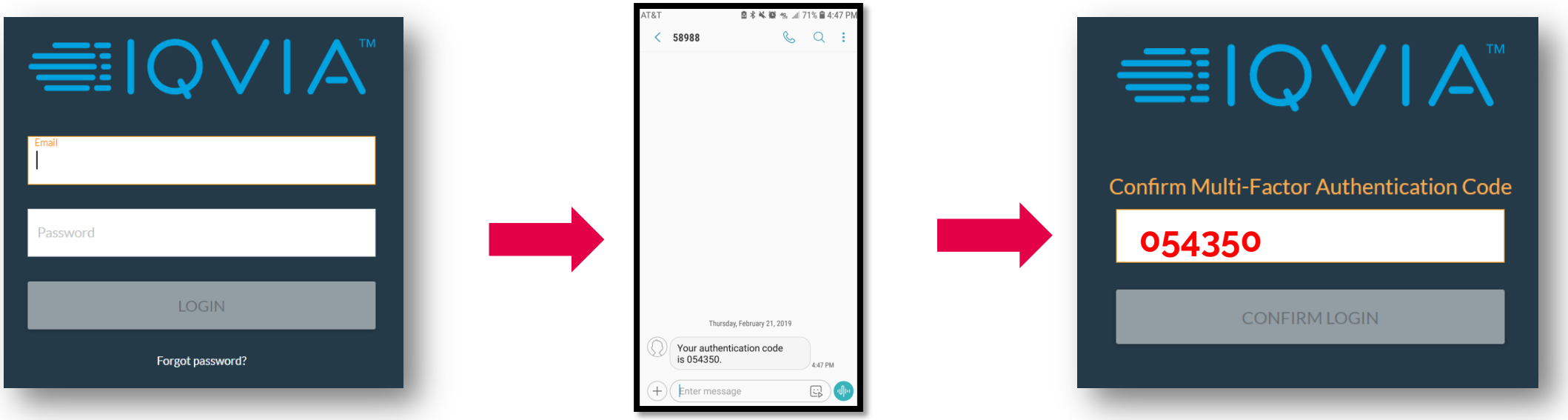
- Site personnel will receive an email from **no-reply@iqvia.com**, providing email and initial password for log-in.
- Use the credentials for logging in to the Web Portal URL, mystudy.altavozclinical.com.
- Set a new password and verify your email with a confirmation code.

Accept Terms & Proceed

- After entering your credentials, accept the End User Terms & Conditions
- Accept the Privacy Policy.
- You are now able to access the Web Portal for your study.

THE WEB PORTAL – MULTI-FACTOR AUTHENTICATION

+ IQVIA's eCOA Web Portal uses Multi-Factor Authentication (MFA) login for all users (sites, CRAs, etc.)
+ A cell phone number is required for MFA login.
+ An authentication code is required for each time the user is logging into the web portal.

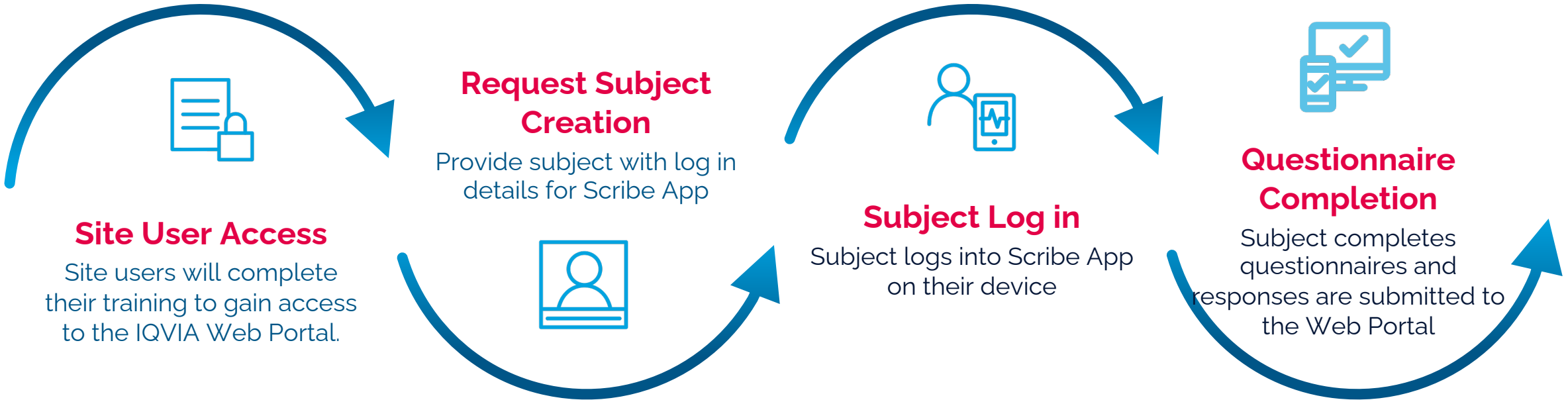


Subject Creation in the Web Portal

Template No.: ECT_TP_TR0003 Revision 4
Effective Date: 02Jun2023

Reference: ECT_WI_TR0004

THE WEB PORTAL – SUMMARY



REQUESTING SUBJECT ACCOUNT CREATION

- Site staff must contact eCOA Customer Care team to request new subject account creation in the eCOA portal (Sculptor).

The following information must be supplied to the customer care team for the subject to be created:

- **Subject ID** – The subject ID must be in the correct format for the study (6 digits).
- **Time-zone** – Indicate the subject's location for this study it is either United States or Puerto Rico
- **Device** – Indicate if the subject is using BYOD (Bring your own device) or provisioned
- **Site** –The site number the subjects is assigned to from the dropdown.
- **Language** – The appropriate language for the subject
- **Schedules** – Inform the customer care team which treatment arm the subject is enrolled to from the following options: (in the event, subject enrolled to the in-correct treatment group, contact the eCOA helpdesk to have this amended
    - **VH3810109 IV Q4M + CAB IM QM**
    - **VH3810109 + rHuPH20 SC Q4M + CAB IM QM**
    - **Standard of Care**

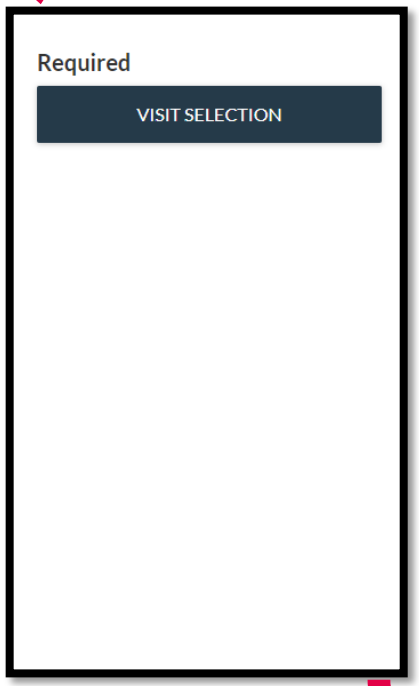
Site Experience using Scribe App

Template No.: ECT_TP_TR0003 Revision 4
Effective Date: 02Jun2023

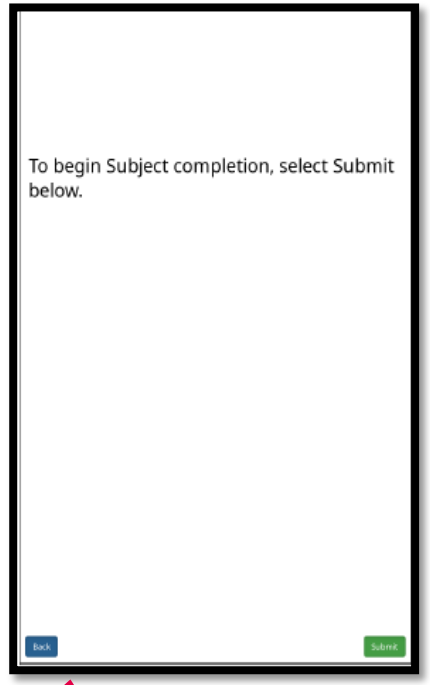
Reference: ECT_WI_TR0004

THE SCRIBE APP – ACTIVATING VISITS

Log in as site staff and select target subject ID to activate their visit



Select subject visit using drop down menu



Select submit to activate the visit

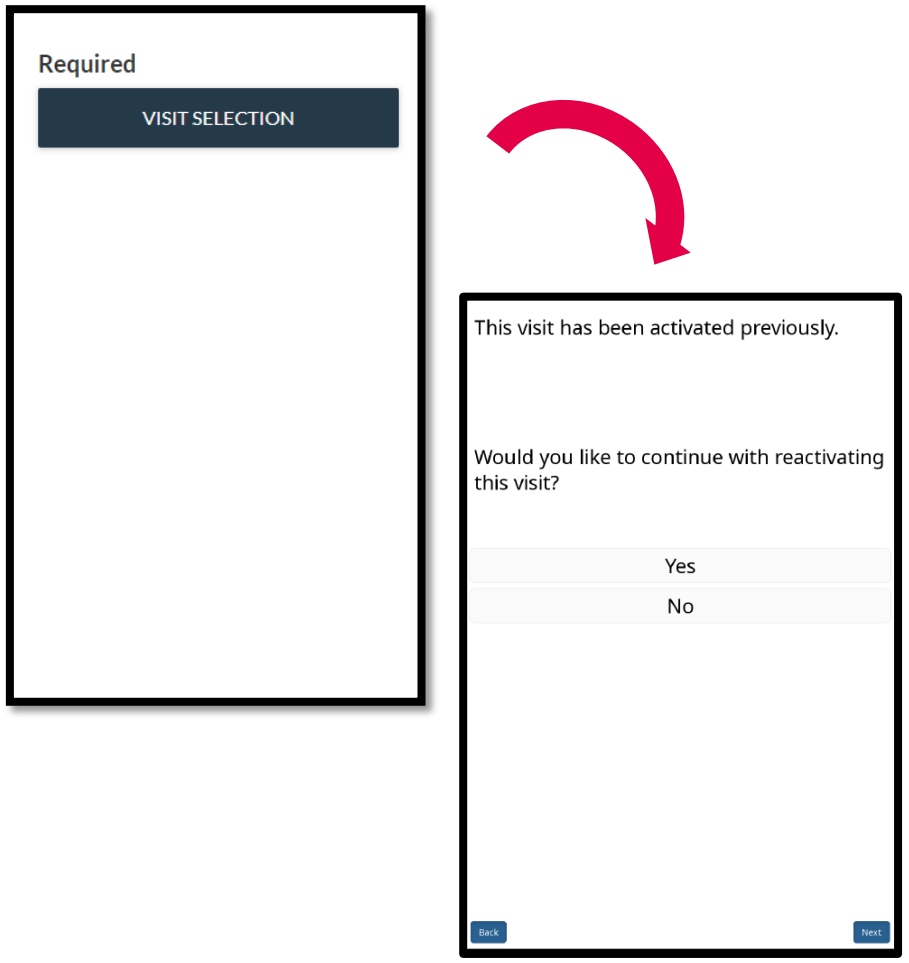
THE SCRIBE APP – ACTIVATING/RE-ACTIVATING VISITS

During each subject site visit, the site staff **must** activate the visit in the provisioned tablet.

- Visit activation **must** occur when the subject is present
- Once a visit is activated, you must instruct the subject to login into their BYOD or provisioned device to complete their visit questionnaires
- Ensure the subject is completing the appropriate questionnaire before and after their injection or infusion

Reactivating Visits:

- Visit can be re-activated in the event a visit was activated by error
- Site to raise data query to delete any duplicate visit activated

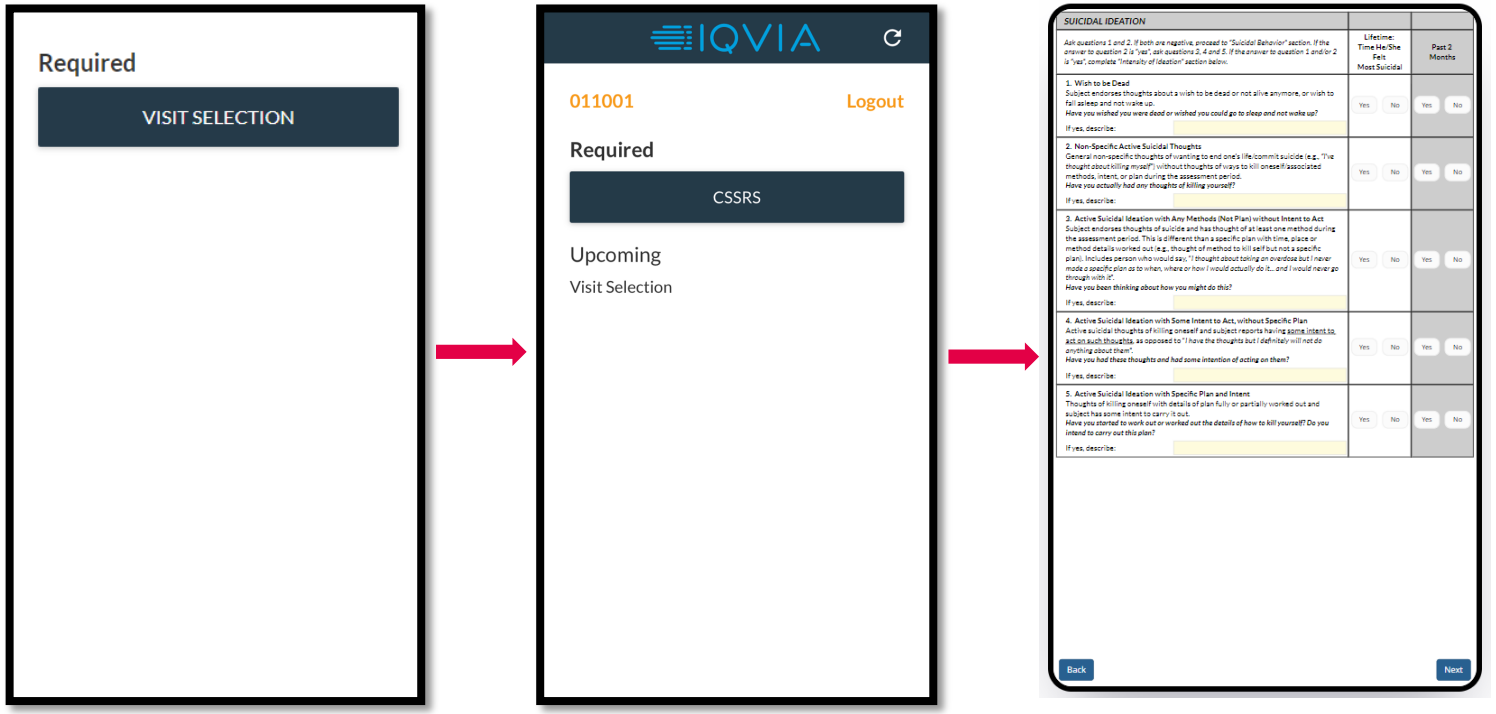


THE SCRIBE APP – C-SSRS

All site staff must be certified in completing the C-SSRS, you can access the training using the highlighted below

URL link:
https://cssrs.columbia.edu/training/training-options/

- Site staff must complete the C-SSRS as per the protocol schedule of events
- Site Staff must activate the visit via the Scribe App (Provisioned tablet) to access the C-SSRS



The Subject Experience using the Scribe App

Template No.: ECT_TP_TR0003 Revision 4
Effective Date: 02Jun2023

Reference: ECT_WI_TR0004

THE SCRIBE APP – LOGGING IN AS A SUBJECT

User Downloads Scribe App

- The Scribe App is downloaded from the Apple Store or Google Play Store.
- Once installed, Scribe will show up as an application on the subject's device.
- Tap on the application to access.

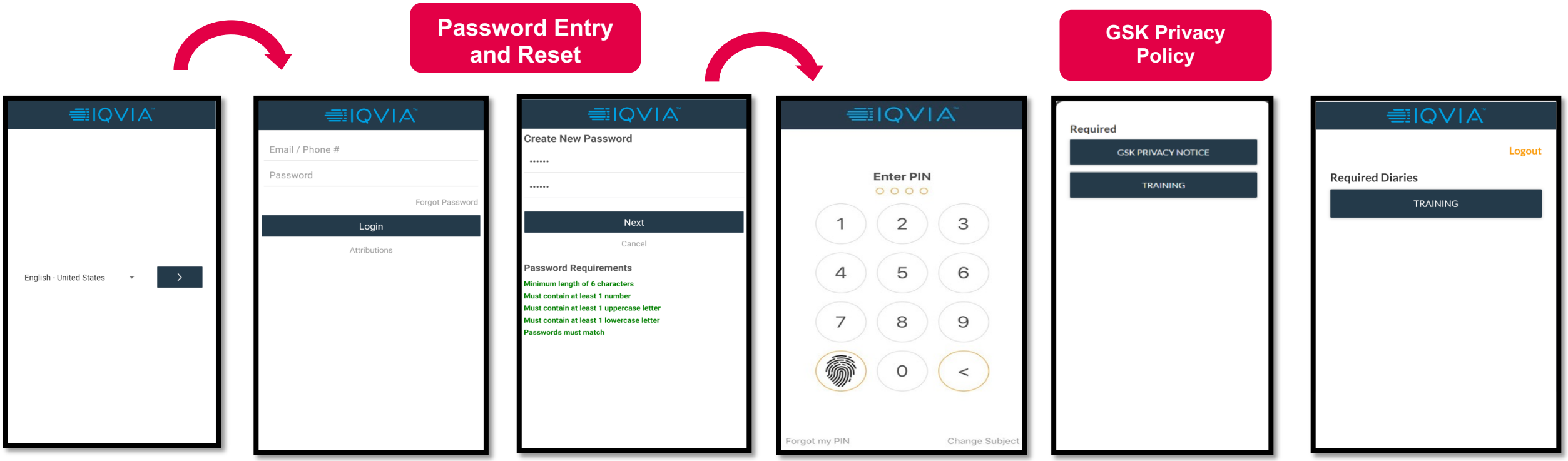
Provided Temporary Password

- Site user to provide subject with temporary email and App password.
- When accessing application, select region and language.

Login to the Scribe App

- Subject to enter temporary email and initial password, triggering password reset.
- **Subject resets new password and enters 4-digit PIN.**
- Subject Reads and Acknowledge GSK Privacy Policy
- Subject completes Training Diary.

THE SCRIBE APP – THE LOGIN PROCESS



THE SCRIBE APP – INJECTION SITE REACTION DAILY EDIARY

Only the subjects enrolled to the following treatment arm must complete the Injection Site Reaction (ISR) Diary Card

- VH3810109 IV Q4M + CAB IM QM
- VH3810109 + rHuPH20 SC Q4M + CAB IM QM

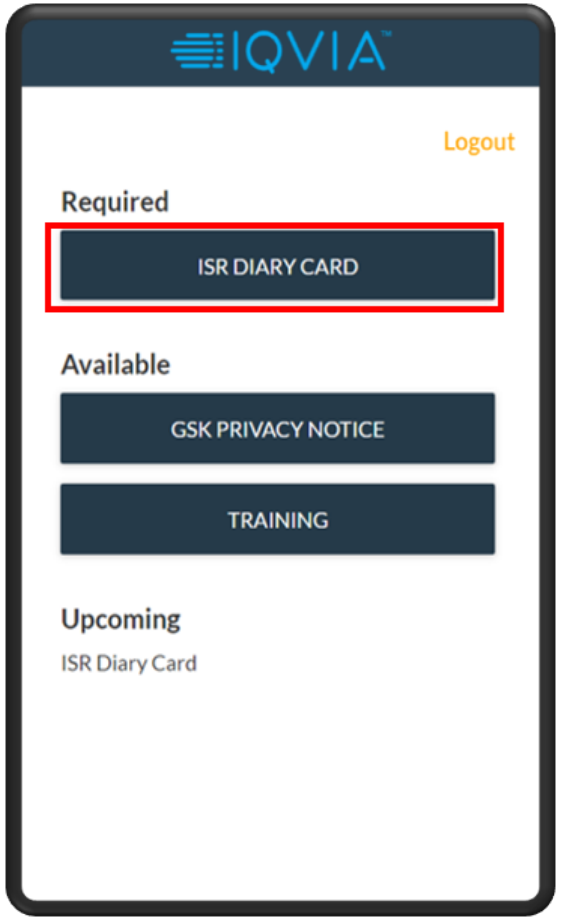
The ISR is a daily diary will contain questions about the subjects' symptoms at the area of inject site.

- Subject to complete assessment **AFTER** their injection
- The subject must complete the diary at home for a duration of 14 days
- The questionnaire will be available to complete by the subject once the site staff has activated the appropriate visit
- Questionnaire activated at Day 1 Baseline and Month 4 visit

Notifications:

- The subject will receive reminders from the Scribe App at 21:00 to complete their eDiary.

The subject MUST complete this questionnaire AFTER their injection or infusion



THE SCRIBE APP – IMPLEMENTATION SCIENCE QUESTIONNAIRE

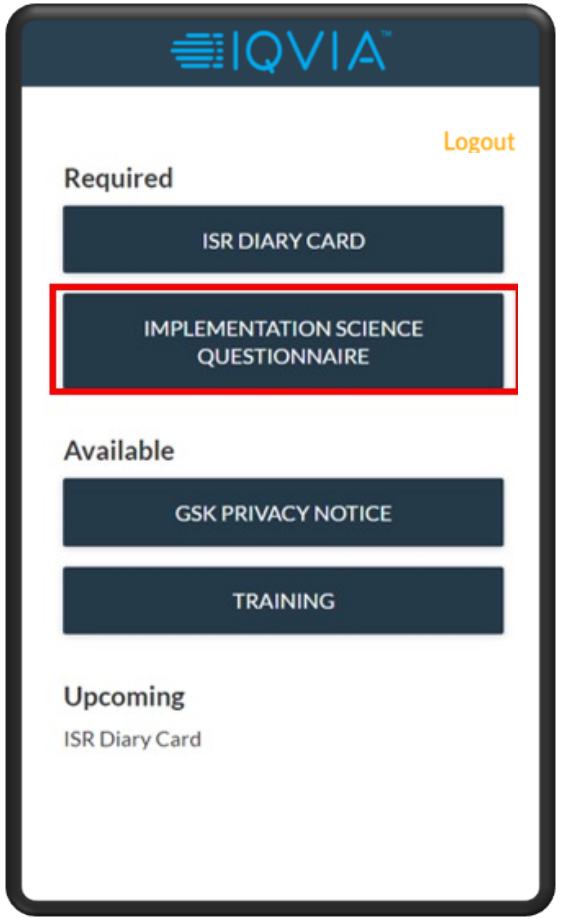
Only the subjects enrolled to the following treatment arm must complete the Injection Site Reaction (ISR) Diary Card

- VH3810109 IV Q4M + CAB IM QM
- VH3810109 + rHuPH20 SC Q4M + CAB IM QM

The eDiary will contain questions intended to understand subjects' perceptions of the injection treatments.

The eDiary will be available to complete once activated by the site staff

- Diary to be completed at Week 1, Month 6 and Month 24
- The eDiary can be resumed until midnight once started.



THE SCRIBE APP – HIVTSQ

Subjects in all Treatment groups is expected to complete the HIVTSQ assessment

The questionnaire must be completed **BEFORE** subject receives their injection and/or infusion

Each question within the HIVTSQ questionnaire is mandatory. In the event subject selects 'NEXT' without selecting a response

- They will be instructed to ***Please Choose** a response
- If the subject did not want to answer the question they can select **'Prefer not to respond'**

The eDiary will be available to complete once the visit is activated by the site

- Diary to be completed at Week 1, Month 6 and Month 24
- The eDiary can be resumed until midnight once started.

Reviewing Subject Responses and Reports in the Web Portal

Template No.: ECT_TP_TR0003 Revision 4
Effective Date: 02Jun2023

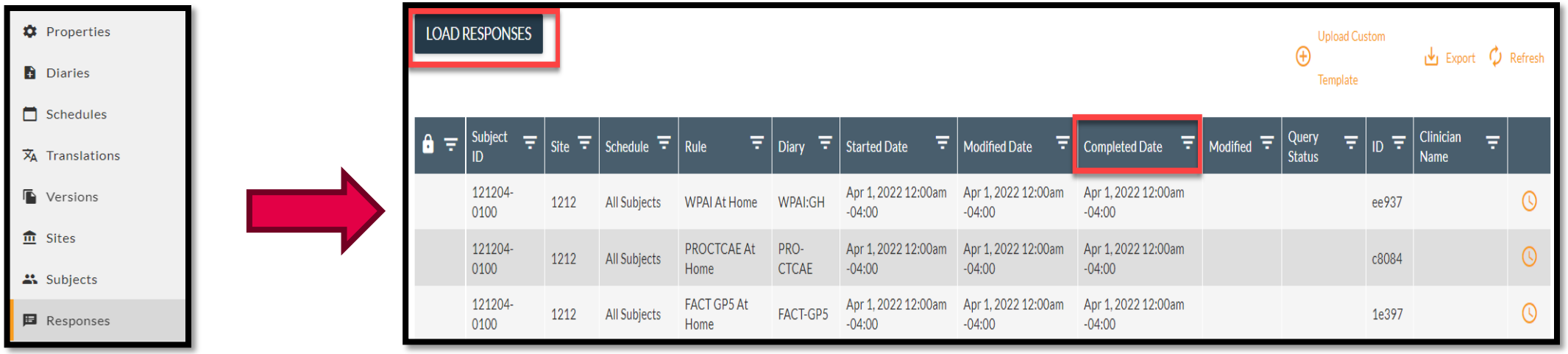
Reference: ECT_WI_TR0004

THE WEB PORTAL – SUBJECT RESPONSES

+ Selecting the **Responses** tab in the Web Portal I allows site users to view individual subject response records for the assessments received from the Scribe App.

+ **Dates of completion** are provided. The responses can also be **filtered by selecting any of the column headers** at the top of the table.

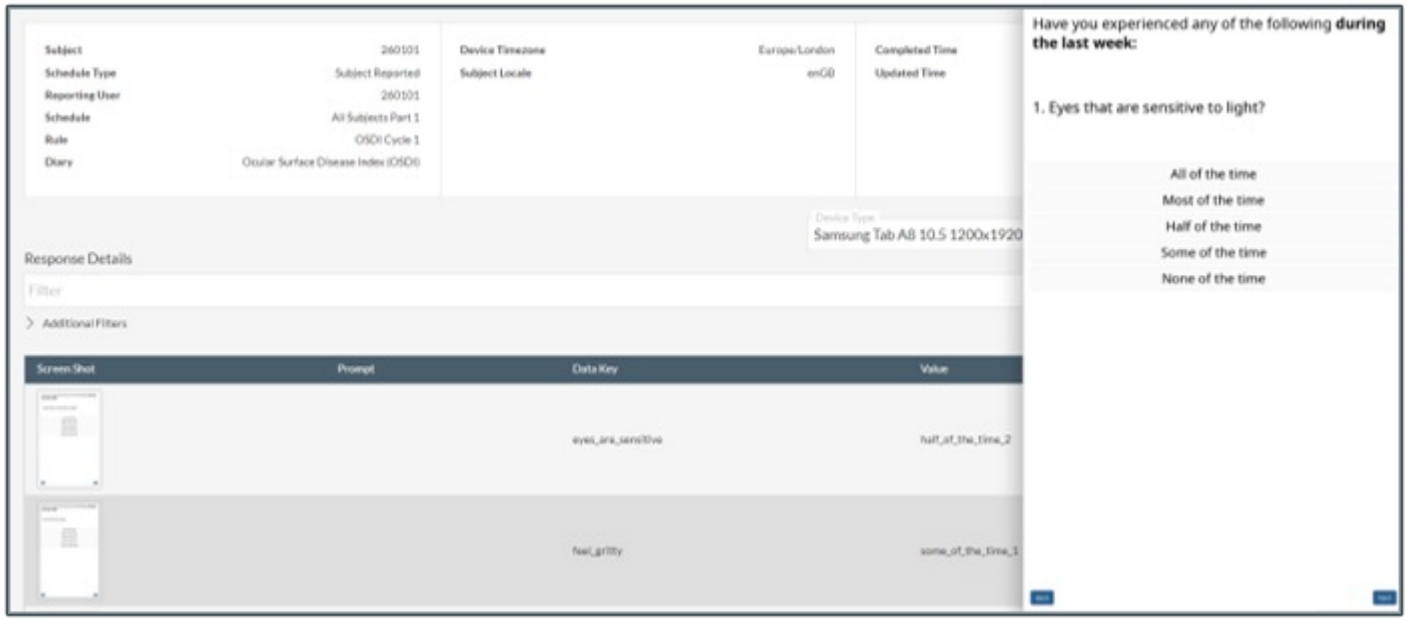
+ **Click** on **LOAD RESPONSES** to load the most recent set of responses onto the screen. The **default view** only lists responses completed in the last **30 days**. Change the filter **Completed Date** Field that is highlighted to load responses **older than 30 days**.



INDIVIDUAL SUBJECT RESPONSE RECORDS

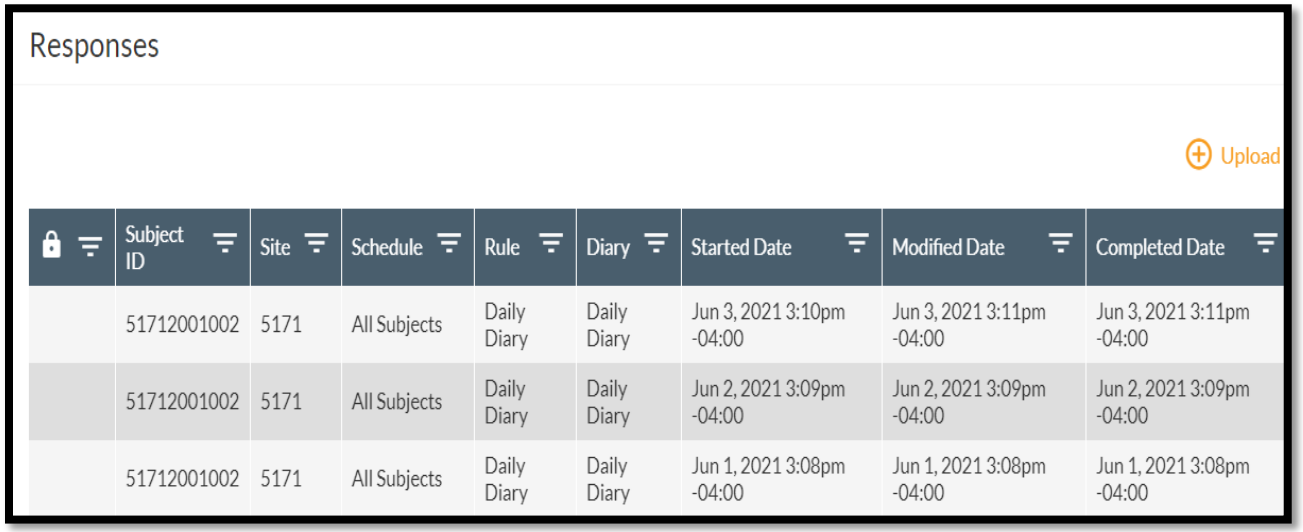
+ Selecting an **individual daily eDiary** will display metrics (in the form of data keys) for each question response.

+ Scrolling down, individual **daily eDiary** pages, with data keys and their associated response values will be displayed for site user review. Selecting a screenshot will allow the site user view the same Scribe App screen that the subject sees when completing the eDiary.



VERIFYING SUBJECT COMPLIANCE

- It is imperative that **regular checks** are made for subject responses in the Web Portal to monitor subjects compliance
- The simplest way to verify daily compliance is to sort by a particular subject on the **Responses** page and **verify daily eDiary completion and upload date**. **Response Reports** can also be reviewed.
- In the below example, **subject 51712001002** is compliant as of 03Jun2021, as they have completed their daily eDiary each day since their vaccination (which took place on the 1st).



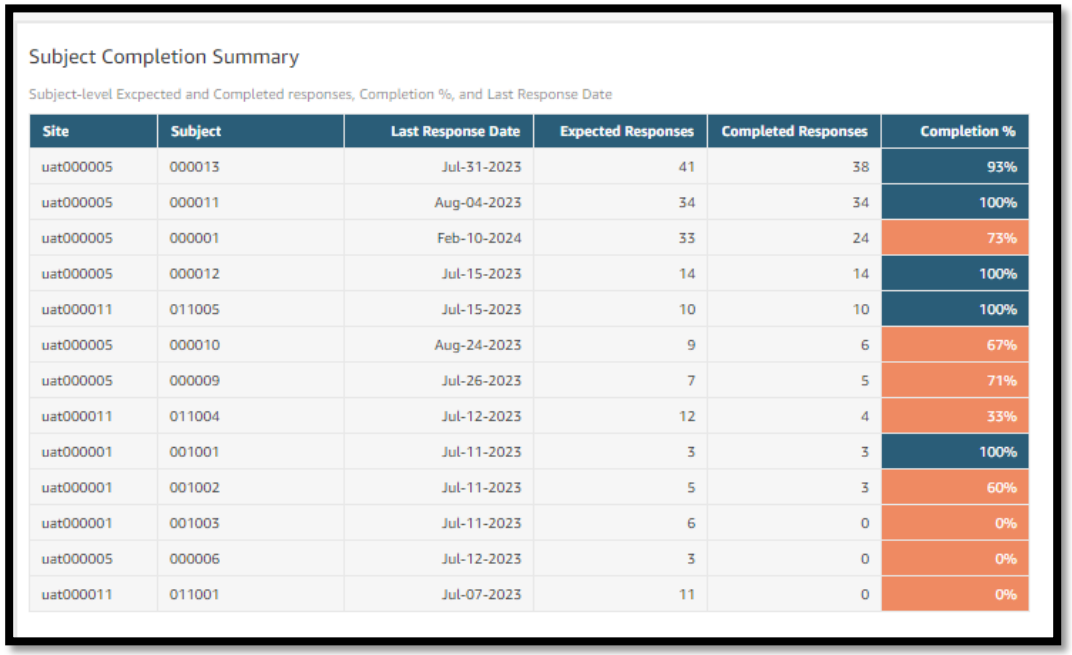
Subject ID	Site	Schedule	Rule	Diary	Started Date	Modified Date	Completed Date
51712001002	5171	All Subjects	Daily Diary	Daily Diary	Jun 3, 2021 3:10pm -04:00	Jun 3, 2021 3:11pm -04:00	Jun 3, 2021 3:11pm -04:00
51712001002	5171	All Subjects	Daily Diary	Daily Diary	Jun 2, 2021 3:09pm -04:00	Jun 2, 2021 3:09pm -04:00	Jun 2, 2021 3:09pm -04:00
51712001002	5171	All Subjects	Daily Diary	Daily Diary	Jun 1, 2021 3:08pm -04:00	Jun 1, 2021 3:08pm -04:00	Jun 1, 2021 3:08pm -04:00

VERIFYING SUBJECT COMPLIANCE CONTI..

Diary Completion Report

+ This report provides information about the completion status of subject diaries for the study.

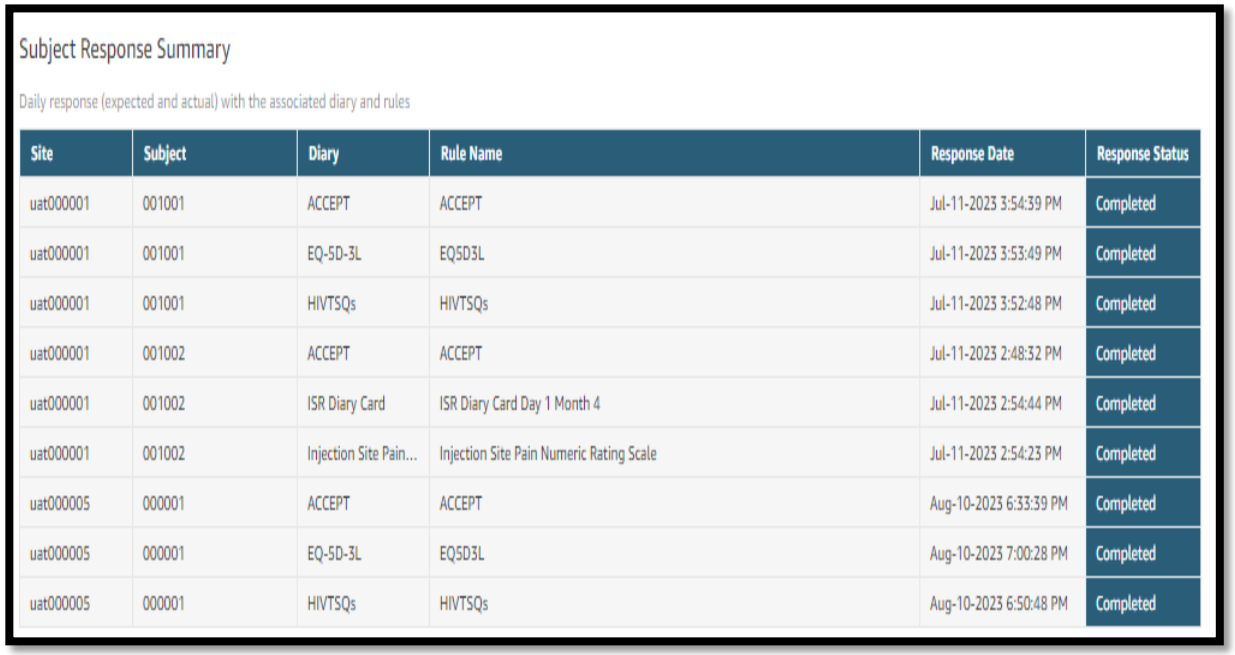
+ It is recommended to conduct **regular checks** on this report to monitor the subject diary completion during site visits and their completion of the ISR daily diary



Subject Completion Summary

Subject-level Excpected and Completed responses, Completion %, and Last Response Date

Site	Subject	Last Response Date	Expected Responses	Completed Responses	Completion %
uat000005	000013	Jul-31-2023	41	38	93%
uat000005	000011	Aug-04-2023	34	34	100%
uat000005	000001	Feb-10-2024	33	24	73%
uat000005	000012	Jul-15-2023	14	14	100%
uat000011	011005	Jul-15-2023	10	10	100%
uat000005	000010	Aug-24-2023	9	6	67%
uat000005	000009	Jul-26-2023	7	5	71%
uat000011	011004	Jul-12-2023	12	4	33%
uat000001	001001	Jul-11-2023	3	3	100%
uat000001	001002	Jul-11-2023	5	3	60%
uat000001	001003	Jul-11-2023	6	0	0%
uat000005	000006	Jul-12-2023	3	0	0%
uat000011	011001	Jul-07-2023	11	0	0%



Subject Response Summary

Daily response (expected and actual) with the associated diary and rules

Site	Subject	Diary	Rule Name	Response Date	Response Status
uat000001	001001	ACCEPT	ACCEPT	Jul-11-2023 3:54:39 PM	Completed
uat000001	001001	EQ-5D-3L	EQ5D3L	Jul-11-2023 3:53:49 PM	Completed
uat000001	001001	HIVTSQs	HIVTSQs	Jul-11-2023 3:52:48 PM	Completed
uat000001	001002	ACCEPT	ACCEPT	Jul-11-2023 2:48:32 PM	Completed
uat000001	001002	ISR Diary Card	ISR Diary Card Day 1 Month 4	Jul-11-2023 2:54:44 PM	Completed
uat000001	001002	Injection Site Pain...	Injection Site Pain Numeric Rating Scale	Jul-11-2023 2:54:23 PM	Completed
uat000005	000001	ACCEPT	ACCEPT	Aug-10-2023 6:33:39 PM	Completed
uat000005	000001	EQ-5D-3L	EQ5D3L	Aug-10-2023 7:00:28 PM	Completed
uat000005	000001	HIVTSQs	HIVTSQs	Aug-10-2023 6:50:48 PM	Completed

Data Changes/Queries

DATA CHANGES

1) A data query via the eCOA Web Portal can be raised to correct or update any **incorrect values entered by subjects or clinicians in questionnaires or diaries.** This method is automated, making it simple for site user(s) or clinicians to request a change.

2) The eCOA Customer Care team must be contacted via email for any **metadata or demographic changes** requests (i.e. changes to site number, subject number or any other changes related to the subject demographic information (language, schedule, time zone).

3) Soft Delete functionality can be used to mark diary data as deleted in the Sculptor web portal e.g., if an assessment has been completed under the incorrect Subject ID or to remove duplicate data. This functionality only allows entire forms/assessments or diary entries to be deleted. Individual responses cannot be removed.

Helpdesk and Support

IQVIA CUSTOMER CARE

- **IQVIA's *Customer Care* is available to site users for technical support:**
  - Site staff should reach out to the Customer Care for technical assistance.
  - Specific telephone numbers for Customer Care vary by country; these are included in the **eCOA Site Manual.**
- **Have the following information available when calling the Customer Care:**
  - Sponsor of the study
  - Protocol number
  - Site number
  - Subject number
- **If issue is not urgent, IQVIA Customer Care can be reached at ecoahelpdesk@iqvia.com**
- **IQVIA Customer Care is available to subjects for technical questions:**
  - subjects should reach out to the Customer Care for technical assistance
  - Specific telephone numbers for Customer Care vary by country; these are included in the **eCOA Site Manual.**

FAQ

FREQUENTLY ASKED QUESTIONS

+ **How do I check if data was transmitted successfully to the eCOA database?**
  - You can see the data by logging into the eCOA Web Portal.
  - Please make sure your subject always selects **Submit** at the end of their diaries.
  - Once done, the device will start to transmit data in the background and will load the main menu. The subject should allow the main menu to load, then wait few minutes prior to closing the app.
  - As a reminder, **subjects should also ensure the device is charged and has a good Cellular or Wi-fi connection. It is therefore recommended to connect to Wi-Fi when available.**

+ **What if my subject forgets their PIN?**
  - If the password and/or PIN is forgotten, Please call the **eCOA Customer Care** to retrieve the password and/or PIN for your subject.

FREQUENTLY ASKED QUESTIONS

+ **What shall I do if my subject has lost or broken their provisioned device?**
  - Please contact your monitor to order replacement provisioned devices. Also contact your monitor if additional supply of provisioned devices is needed.

+ **Can the eCOA device be reused?**
  - Yes. Please ask the Customer Care for help resetting your device for a new subject.
  - Device cleaning instructions are also provided at the start of the study.
  - **For reused provisioned devices, site users should follow the instructions detailed in the eCOA Study Manual for Data Transfers from the Scribe App prior to reset.**

+ **What happens if the subject accidentally deletes the Scribe App, or replaces their smartphone device?**
  - The subject should be instructed to contact the site users if this takes place; the site users should walk the subject through redownloading the App and logging in. Their eDiaries will still be available.

Thank You!

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IMPLEMENTATION SCIENCE

Cassidy Gutner, PhD

Implementation Science Lead

WHAT IS IMPLEMENTATION SCIENCE AND WHY IS IT PART OF EMBRACE?

WHAT IS IMPLEMENTATION SCIENCE?

Translating innovative scientific discoveries…

…into routine clinical practice

Eccles MP and Mittman BS. Implement Sci 2006;1:1

WHY IS IT PART OF EMBRACE?

INNOVATION --> IMPACT

- Even the most innovative discoveries do not automatically translate into real world impact
- It takes an average of 17 years for a new intervention to get broadly used and make a public health impact
- Slow uptake is often a result of products not fitting within the context in which they are used and people that could use them not being able to easily integrate it into existing systems
- Inclusion of implementation science design early in the pipeline can support a better fit of a product that has a greater likelihood of making an impact post-approval

Overall Objective

To assess patient and staff experiences with two forms of administration of N6LS (SC vs. IV) in a Phase 2 HIV trial

1. What is the patient and staff experience of N6LS IV & SC implementation?

2. What are the facilitators and barriers for successful implementation of N6LS IV &SC ?

3. What is the patient and staff experience of N6LS IV and SC administration?

IMPLEMENTATION SCIENCE OBJECTIVES AND ENDPOINTS

IMPLEMENTATION SCIENCE ASSESSMENTS

EXPLORATORY

Objectives

Participants: To assess acceptability, feasibility, and general fit of N6LS

Staff Study Participants: To assess acceptability, feasibility and support needed for successful implementation

Endpoints

- Measured via questionnaires at Day 1, Month 6, and Month 24
- Qualitative interviews at Month 6

- Measured at Month 6 via brief quantitative questionnaires
- Qualitative interviews at Month 6*

IMPLEMENTATION SCIENCE COMPONENTS

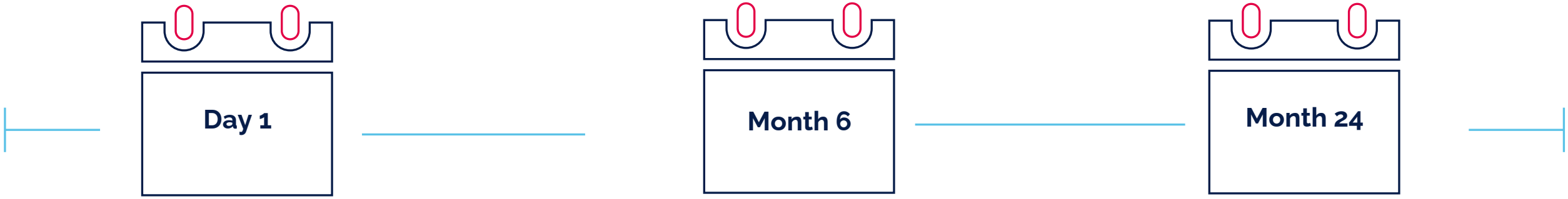
1

Participants Questionnaires & Interviews

2

Staff Study Participant Questionnaires & Interviews

PARTICIPANT ASSESSMENTS
TIMING AND LOGISTICS



Quantitative only

Quantitative and Qualitative *

Quantitative only

- **Quantitative questionnaires** will be collected from participants in the **subcutaneous and intravenous infusion arms** with the other electronic health outcomes assessments
- Across the study we are aiming to collect **qualitative interviews** from 15 participants per investigational arm
  - *Some sites may not have participants selected for interviews
- IQVIA will help guide the study coordinator at each site to select patients for interviews

IMPLEMENTATION SCIENCE COMPONENTS

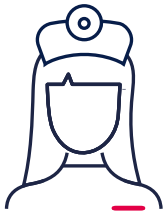
1

Participants Questionnaires & Interviews

2

Staff Study Participant Questionnaires & Interviews

STAFF STUDY PARTICIPANTS
(~3 per site)



Physician/
Principal Investigator

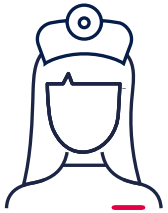
Nurse

Direct Care Provider

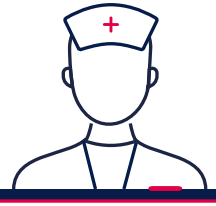
All Staff Study Participants and roles are important

Each participant brings unique expertise especially as we learn about how to make implementation fit into routine care

STAFF STUDY PARTICIPANTS



Physician/ Principal Investigator

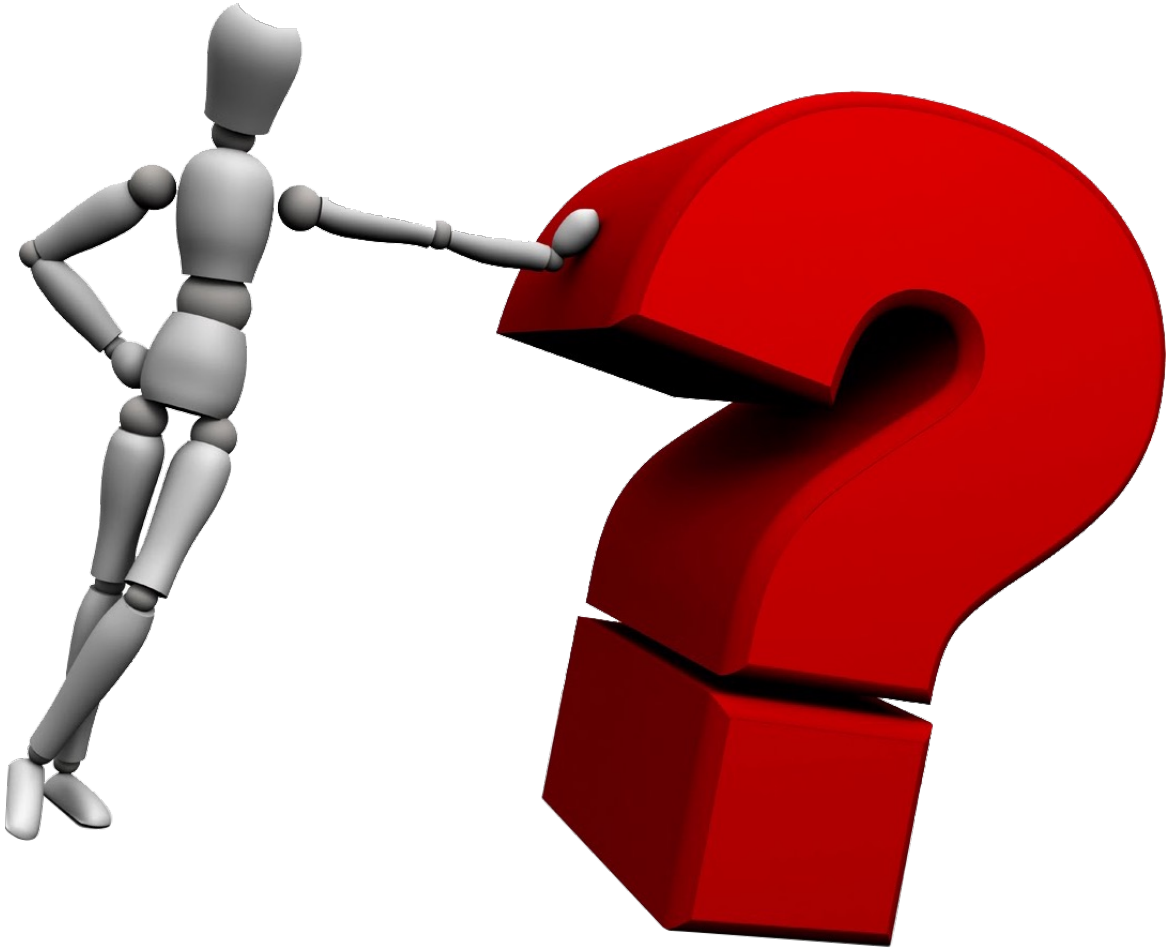


Nurse

Direct Care Provider

- All Staff Study Participant procedures will be part of an appendix to the main protocol
- Assessments will occur at Month 6
- All Staff Study Participants will complete the quantitative questionnaires
- 25 Staff Study Participants will be selected for a qualitative interview
- Interviews will allow for an opportunity to provide detail about how the process works in the study and what might be needed if these treatments are approved to use in routine care
- IQVIA will provide detailed information about the interviews at their operational site training

Questions?



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DATA MANAGEMENT

Anshika Tripathi

Lead Data Manager

AGENDA

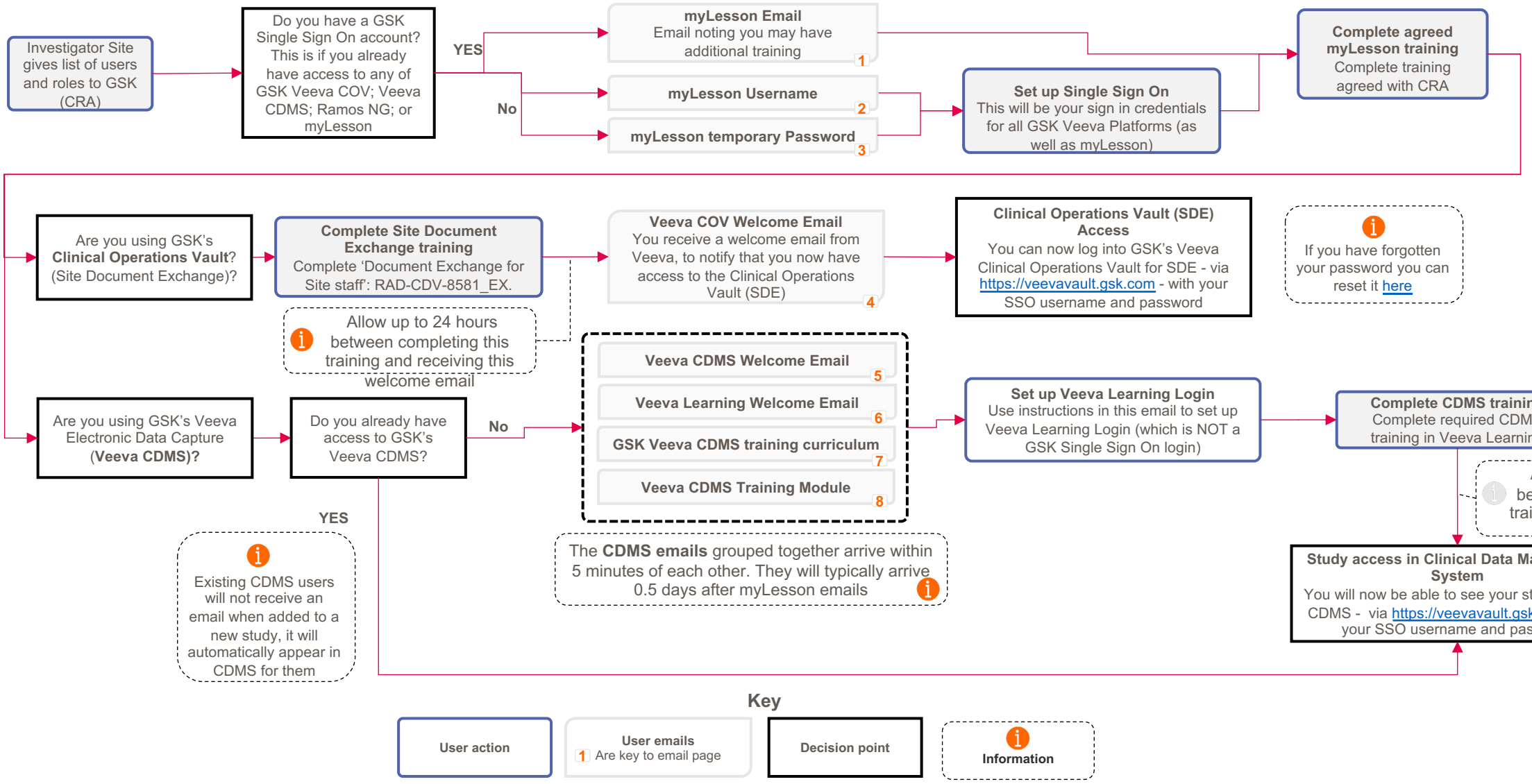
- User access management
- Data Entry and Query Management
- SAE/AE Data Entry and Escalation
- PI signatures
- Veeva CDMS Navigation

User Access management

GSK VEEVA SYSTEMS OVERVIEW

System	What is it used for?	URL required	Username and password	Training platform
GSK Veeva Clinical Data Management Systems (CDMS)	Electronic Data Capture (EDC) - interface for capturing and reviewing clinical trial data.	https://veevavault.gsk.com	GSK Single Sign On username (email address you provided to GSK) and password (set when setting up SSO for the first time) Login details sent by: rd.cshd-access-admin@gsk.com (sent when a user is originally added to myLesson)	Veeva Learning
GSK Veeva Clinical Operations Vault (COV) – Site Document exchange	Site Document Exchange – provides a secure system for GSK to provide clinical study documents to, and collect documents from, the Investigator site	https://veevavault.gsk.com	GSK Single Sign On username (email address you provided to GSK) and password (set when setting up SSO for the first time) Login details sent by: rd.cshd-access-admin@gsk.com (sent when a user is originally added to myLesson)	myLesson
myLesson	Completing GSK training online. Training held within this platform is a pre-requisite for access to GSK Veeva COV (though the training can be done offline)	http://mylesson.gsk.com/	GSK Single Sign On username (email address you provided to GSK) and password (set when setting up SSO for the first time) Login details sent by: rd.cshd-access-admin@gsk.com (sent when a user is originally added to myLesson)	n/a
Veeva Learning	Completing GSK Veeva CDMS training. This training is a pre-requisite for study access within the CDMS Vault. Users can login to GSK Veeva CDMS without doing this training but they will not see their studies until training is complete.	https://learning.veeva.com/	Username: email provided to GSK; password set when setting up Veeva Learning account for the first time. Note: this is not a SSO login (though it is the same username). Login details sent by: team@learn.veeva.com	n/a

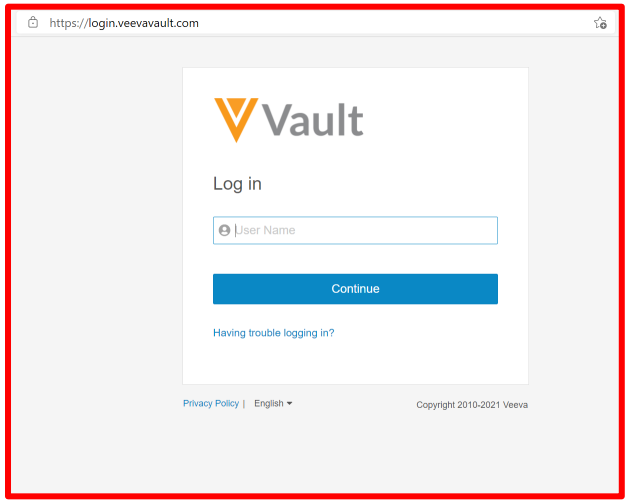
ACCESS FLOW

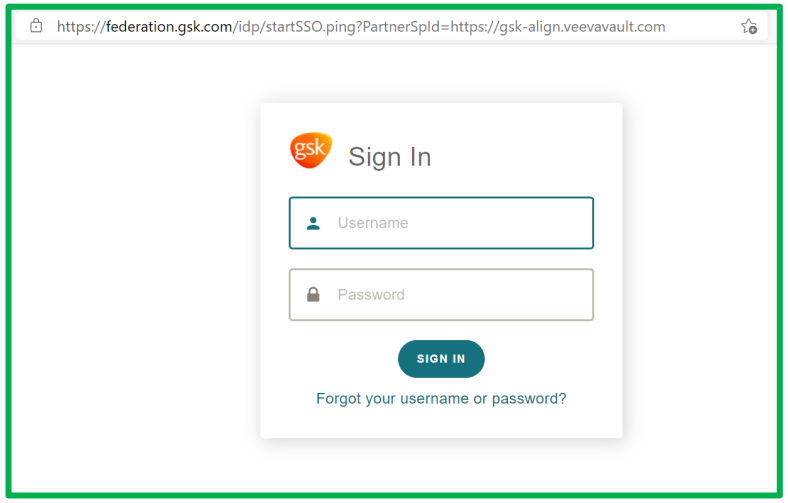

Investigator Site gives list of users and roles to GSK (CRA)
Do you have a GSK Single Sign On account? This is if you already have access to any of GSK Veeva COV; Veeva CDMS; Ramos NG; or myLesson
YES
No
myLesson Email
Email noting you may have additional training
1
myLesson Username
2
myLesson temporary Password
3
Set up Single Sign On
This will be your sign in credentials for all GSK Veeva Platforms (as well as myLesson)
Complete agreed myLesson training
Complete training agreed with CRA
Are you using GSK's Clinical Operations Vault? (Site Document Exchange)?
Complete Site Document Exchange training
Complete 'Document Exchange for Site staff': RAD-CDV-8581_EX.
Allow up to 24 hours between completing this training and receiving this welcome email
Veeva COV Welcome Email
You receive a welcome email from Veeva, to notify that you now have access to the Clinical Operations Vault (SDE)
4
Clinical Operations Vault (SDE) Access
You can now log into GSK's Veeva Clinical Operations Vault for SDE - via https://veevavault.gsk.com - with your SSO username and password
If you have forgotten your password you can reset it here
Are you using GSK's Veeva Electronic Data Capture (Veeva CDMS)?
Do you already have access to GSK's Veeva CDMS?
No
YES
Existing CDMS users will not receive an email when added to a new study, it will automatically appear in CDMS for them
Veeva CDMS Welcome Email
5
Veeva Learning Welcome Email
6
GSK Veeva CDMS training curriculum
7
Veeva CDMS Training Module
8
The CDMS emails grouped together arrive within 5 minutes of each other. They will typically arrive 0.5 days after myLesson emails
Set up Veeva Learning Login
Use instructions in this email to set up Veeva Learning Login (which is NOT a GSK Single Sign On login)
Complete CDMS training
Complete required CDMS training in Veeva Learning
Allow up to 12 hours between completing this training and trial access in CDMS
Study access in Clinical Data Management System
You will now be able to see your studies within CDMS - via https://veevavault.gsk.com - with your SSO username and password
Key
User action
User emails
1 Are key to email page
Decision point
Information

WHAT IS THE CORRECT URL?

- Use this **GSK URL** https://veevavault.gsk.com to log in to GSK's Veeva Vaults (both COV (SDE) and CDMS)
- You **cannot use** the generic Veeva login URL (https://login.veevavault.com)
- If you ever find you are re-directed to this generic login page, you must enter the **GSK** Veeva URL: (https://veevavault.gsk.com) to login
- To easily navigate to the correct GSK each time, you should save https://veevavault.gsk.com as a favourite/bookmark
- Warning: Check the correct URL is saved as the favourite; depending upon your browser, the URL may need to be manually edited in the favourite/bookmark manager

This Access URL automatically loads when you enter
https://veevavault.gsk.com
You should **NOT** save the access URL as the bookmark





- **Do NOT** bookmark/favourite **the Vault URL** that will appear after you have logged in to a Veeva GSK Vault (COV: https://gsk-clinical-ops.veevavault.com/ and CDMS: https://gsk-cdms.veevavault.com). If you try to login via these URLs, you are automatically redirected to the **generic Veeva login**, which site staff cannot use.

COV (SDE): *Clinical Operations Vault (Site Document Exchange)*
CDMS (EDC): *Clinical Data Management System Vault (Electronic Data Capture)*

VEEVA CDMS TRAINING

In order to access the study, you will need to complete the assigned training curriculum at https://learning.veeva.com/

- **Username:** email address provided to GSK;
- **Password**: set when setting up Veeva Learning account for the first time.
  - Note: this is **not a GSK SSO login** (though it is the same username).
  - *Login details sent by: team@learn.veeva.com*

- You can reset your password (if forgotten or missed welcome email) – By clicking 'Forgot Password' at https://learning.veeva.com/

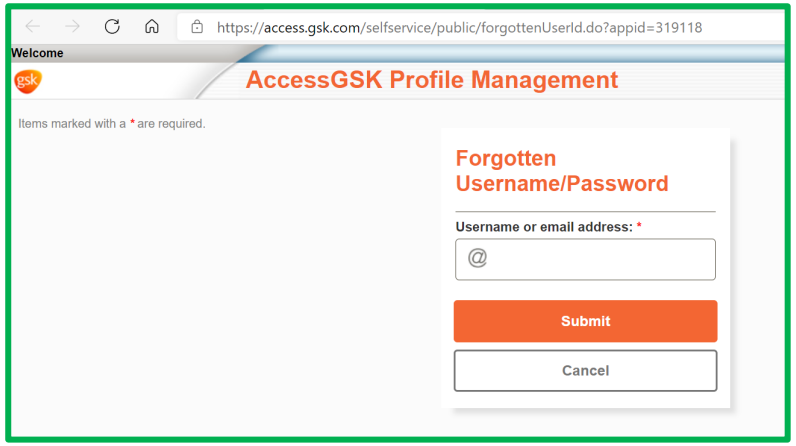
If you are not receiving the emails from *team@learn.veeva.com*

- Have IT staff add the email address team@learn.veeva.com and the domain Veeva.com to users Outlook whitelist. Try following the instructions here: https://clean.email/how-to-whitelist-an-email
- Send an email to GSKClinicalSupportHD@gsk.com to request: Can they please ask Veeva CDMS Support to manually send the user their credentials

HOW DO I RESET MY PASSWORD?

Password reset

- If you have forgotten your password for the GSK Single Sign On (which is used for both CDMS and COV access), you can reset your password here. This takes you to 'Access GSK Profile Management' (right); you should enter the email address you provided to GSK (this is your username for GSK Veeva Vaults).
- Follow the instructions which are sent to re-set your password
- Please contact GSK Clinical Support Helpdesk if you have any issues with this and they can send you a new temporary password
- Likewise, if you have not yet set up your password, and your temporary password has expired (expires after 14 days) please contact the GSK Clinical Support Helpdesk who can reset this.



Incorrect link for password reset

- You **cannot** re-set your password via the generic Veeva login site (https://login.veevavault.com); if you try to reset your password via this site, you will be sent instructions to reset your password for a GSK Veeva username (firstname.lastname@gsk.com) which is not the username/login you need to use to log in to the GSK Veeva Vaults
- Note: if you request a password reset through this method, you may also be sent usernames for Veeva accounts you have with other sponsors (that are associated with your email address)

Data Entry and Query Management

GUIDANCE ON DATA ENTRY IN VEEVA CDMS - TIPS FOR DATA ENTRY

The Event Date is the only data item that cannot be deleted from any visit once it is entered and submitted in the eCRF

Dynamic items are typically questions (i.e.. Is subject eligible? Y/N) that will automatically trigger forms(eCRF) based on the answer. The dynamic forms(eCRF) can be removed by changing the answer prior to data entry and submission of data on the new form (screen).

Dynamic CRFs created by answering a trigger eCRF item can be removed:

If no data is entered and submitted on the dynamically created eCRFs

By changing the answer to the "dynamic question" in the eCRF

All SAE related CONMEDs must also be entered on the study CONMEDS forms within common forms and link them per option available. Any changes to either record must be corrected consistently on both forms or will be queried

Casebook signatures will be explicitly requested when needed before interim analysis, IDMC, final DBL Once a casebook is signed, any new data entry/changes to the eCRF will automatically invalidate the PI signature and require re-signing for key deliverables

DATA QUERY (DQ) PROCESS AND STATUS

Automatically generated immediately after eCRF data is submitted

- Values/date out of expected range/visit window
- Dates/times illogical or not rationally reasonable (ex. Future dates are not allowed)
- Study Assessment date prior to Informed Consent Date

Auto Query

Manually generated during/after GSK review

- Data discrepancy found during review by Site Monitor or DM
- Veeva EDC does not match source (ex. external lab report visit, or dates do not match eCRF data)
- Inconsistent data across eCRFs

Manual Query

Status	Icon	
Open		*Open* indicates that a query has not been answered and needs a response from Site
Answered		*Answered* indicates that a query has been addressed. For example, the site has responded with a reason for the queried value.
Closed	N/A	*Closed* Indicates that the query response has been reviewed and it requires no further action or discussion. A manual query will be closed by the team (member) who opened it. An auto query will be automatically closed as data is updated with a value no longer generating a discrepancy or inconsistency. If value is not changed and discrepancy remains, DM to review query answer and close or re-query accordingly.

SAE/AE Data Entry and Escalation

SERIOUS ADVERSE EVENTS (SAES) REPORTING AND ENTRY

- Investigator/sites are instructed to complete paper SAE reporting forms with all initial SAE information and follow-up information and send them to GSK via email OAX37649@gsk.com or via fax to +44 2087547822 **within 24 hours of awareness**

- All AEs and SAEs, including AEs leading to withdrawal and pregnancy reports will be captured in Veeva CDMS
- Investigator/sites are also instructed to then enter all initial **SAE information** and follow-up information, into the **Veeva CDMS a**s per data entry timelines for the study.

SERIOUS ADVERSE EVENTS (SAE) BACK-UP PAPER FORM

In the event a SAE occurs and Veeva CDMS is not available, the SAE must be reported using the back-up paper process

Process Flow

- CRAs to share this form with sites which is available in the vTMF (Veeva COV)

- Investigator/sites fill in Paper CRF with the data available

- Send the form to GSK PV Ops: OAX37649@gsk.com (or fax +44 208 754 7822)

- If paper back-up is used, the SAE should be entered into CDMS within

SERIOUS ADVERSE EVENTS (SAE)

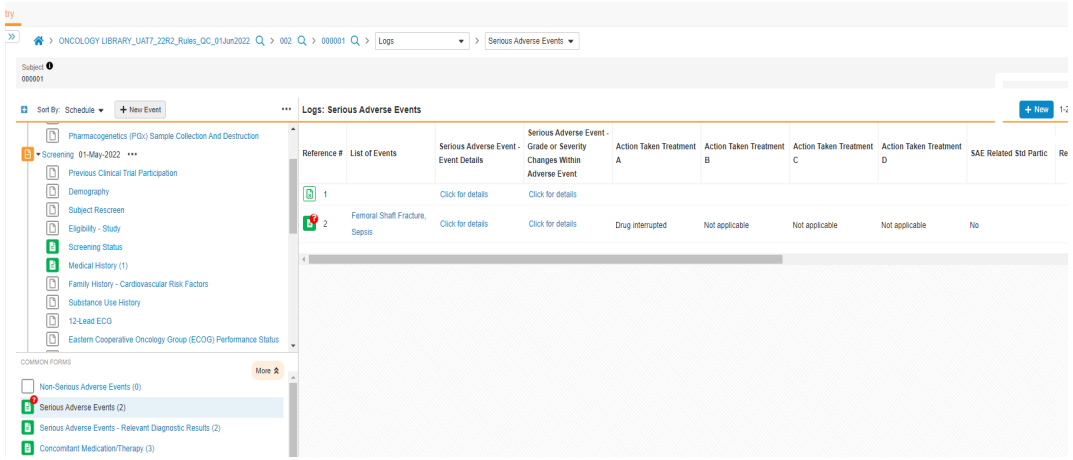
- The correct data entry of **SAEs** is required to ensure that the critical safety data is transferred to the GSK Safety Database (Argus) for regulatory reporting
- Within Veeva CDMS, you **can link related Forms** through utilising the functionality of 'Form Linking'.
  - For example, if you are in **Concomitant Medication Form** you can link to a SAE, then when you navigate to that particular **Serious Adverse Event Case Form** within Vault, you will see that the CM is already linked.

- **In addition to ensure complete safety event reporting, link the following relevant eCRF records related to SAE:**
  - All Concomitant Medications
  - All Relevant Medical History
  - All Relevant Diagnostic result
  - Relevant Scans
  - Study conclusion- End Of study
  - Treatment discontinuation eCRF

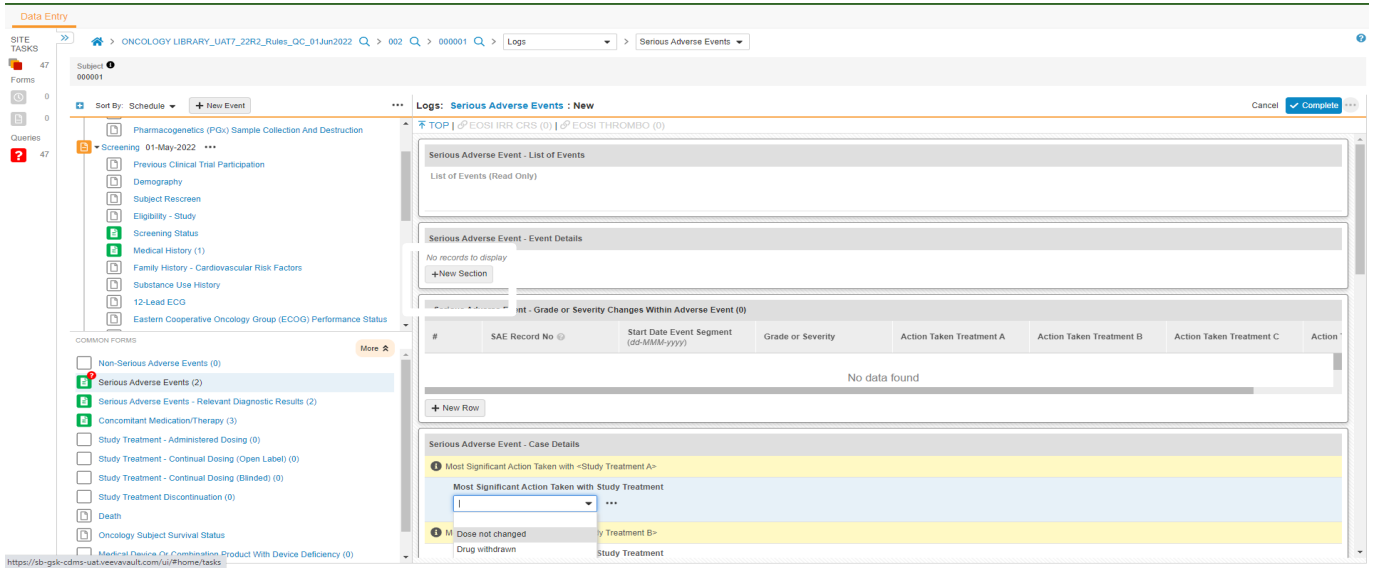
Further information on Form Linking can be found on the Vault CDMS help page and can be accessed here:
General Vault CDMS Help: https://cdmshelp.veeva.com
Help on Form Linking: https://cdmshelp.veeva.com/lr/sites/repeating-forms/#form-linking

HOW TO RAISE A SERIOUS ADVERSE EVENT (SAE)

- To create a new form, navigate to **Serious Adverse Events** and click on the “+ **New**” button.
  Multiple forms can be created in this form set, there should be a new form for each SAE Case.



- All clinically and/or temporally related Serious AEs should be entered separately within the SAE case by selecting “**+New Section**” button within the **Serious Adverse Event - Event Details** section of the form.



PI signatures

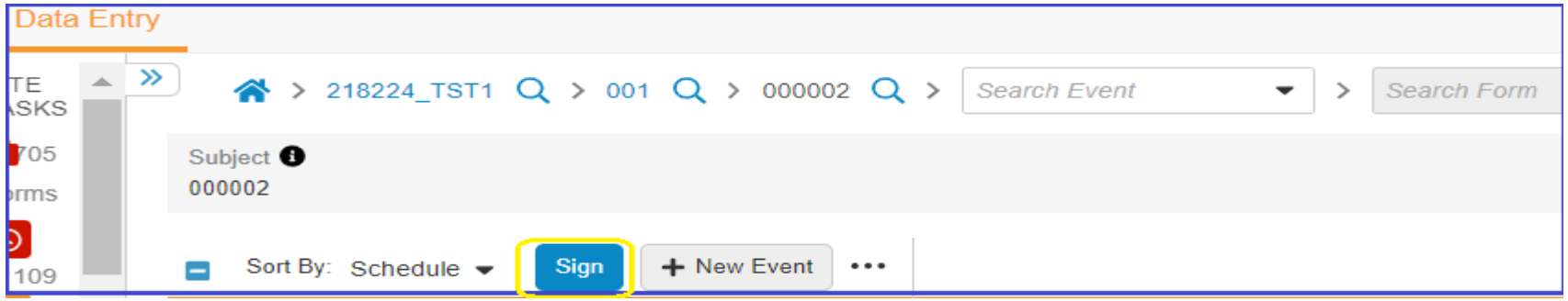
PI SIGNATURES

- Electronic PI signatures in Veeva EDC = handwritten PI signature per GCP and Regulators to confirm the accuracy and completeness of data reported in EDC.
- Vault eSignature meets the requirements of FDA 21 CFR Part 11
- Signatures can be applied at form/events/casebook level
- Required for all subjects, including Screen Failures
- If a subject is relocated to a new site, the PI is responsible for reviewing and signing the casebook prior to transferring the subject
- PI signatures will be explicitly requested during Interim analysis, IDMC (as required) and database lock
- Any update in signed eCRF will break/ invalidate the PI signature and require re-signing

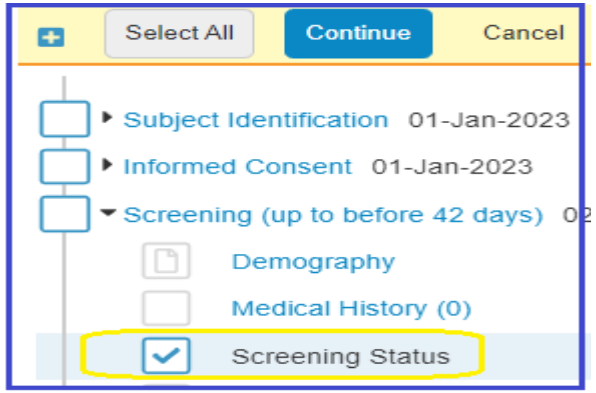
HOW TO SIGN

Login with PI Credentials, after the data entry and subject is clean then complete the signature for the Subject

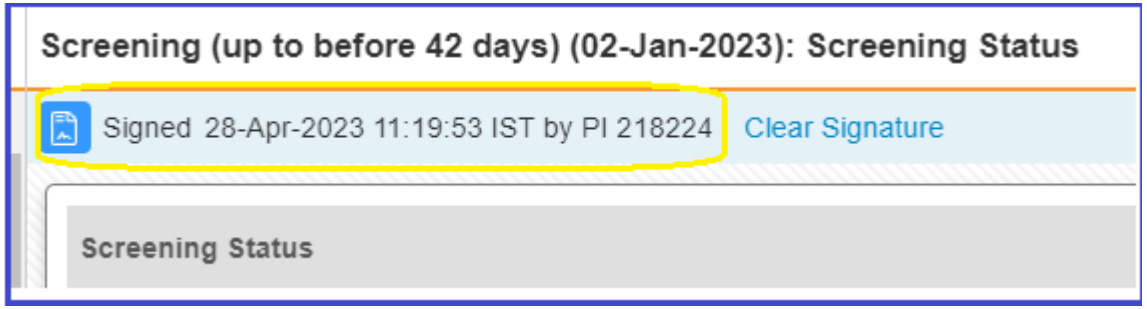
1. Sign option



2. Select the CRFs



3. Continue then enter username and password and complete the signature.

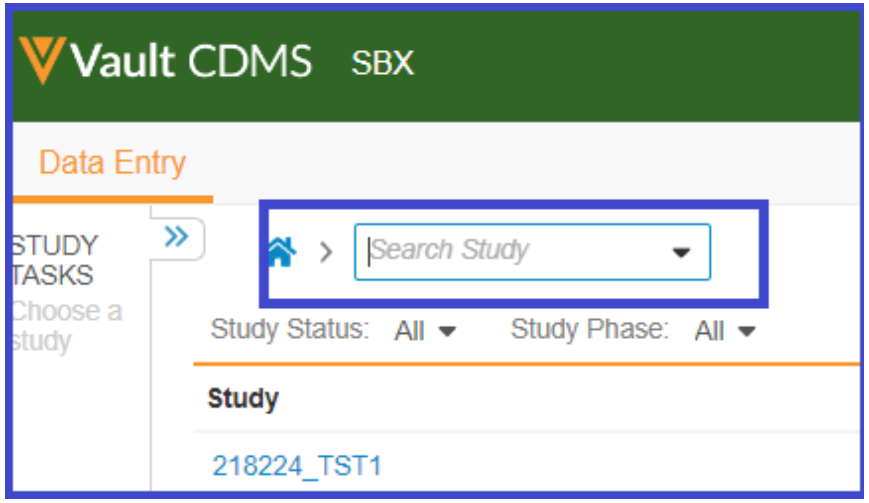


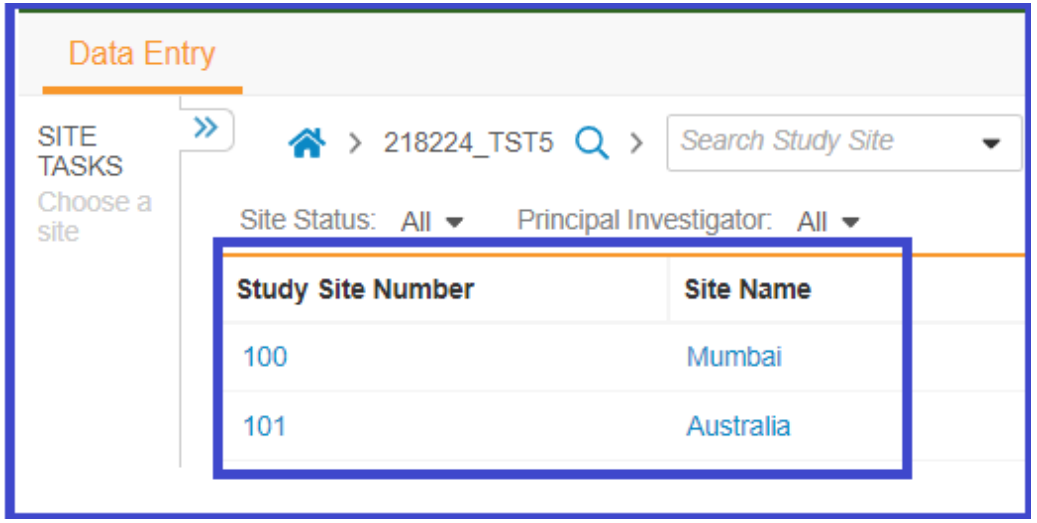
Additional support: Veeva Help page on Providing Signatures (veeva.com)Managing Queries (veeva.com)

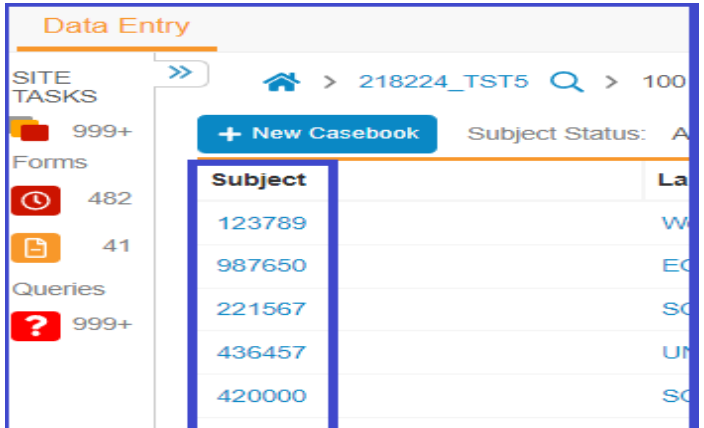
Veeva CDMS Navigation

VEEVA CDMS LOGIN

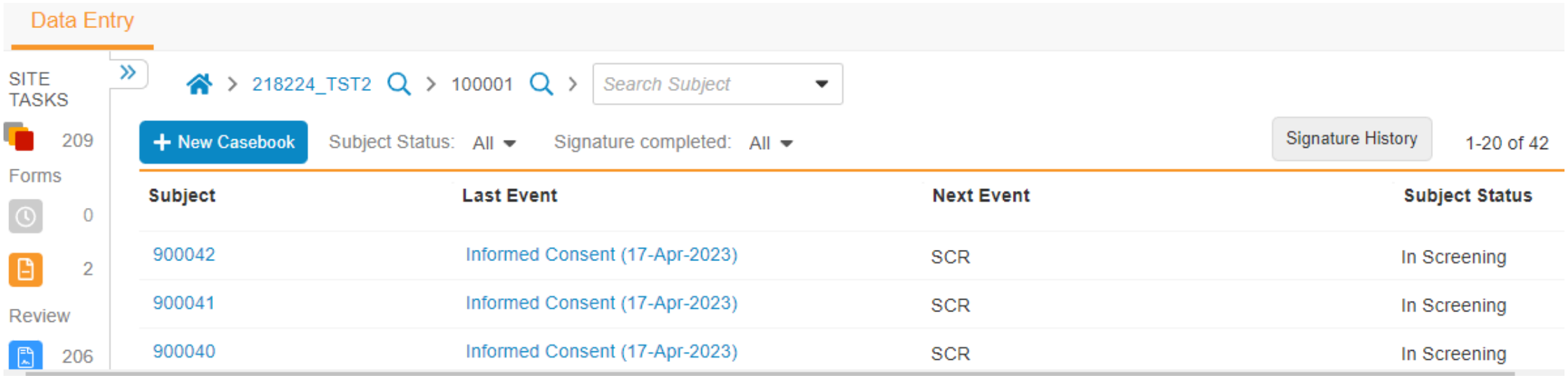
Login to Veeva CDMS using credentials> select the study

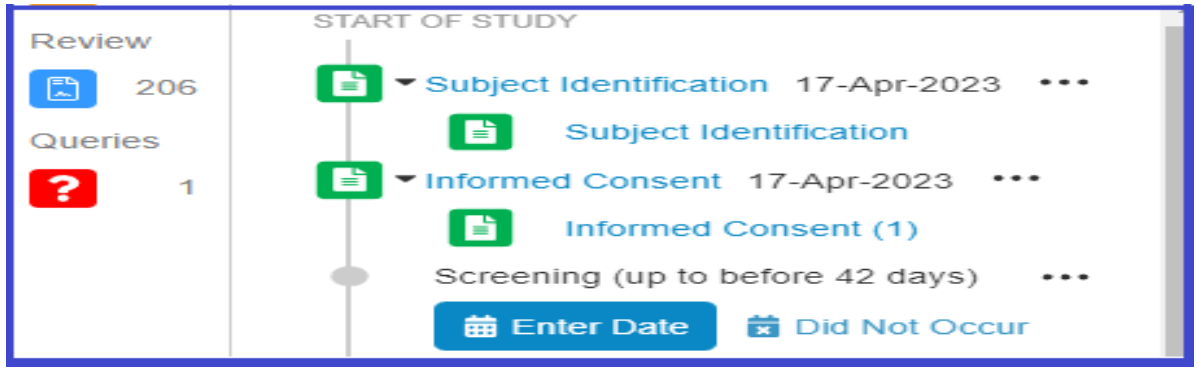






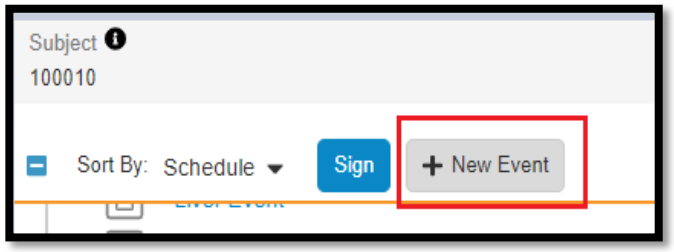
CREATING A SUBJECT (NEW CASEBOOK)

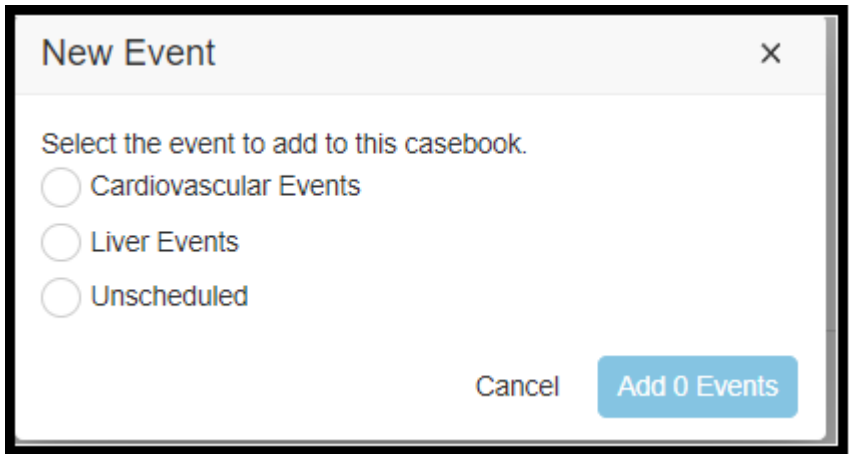




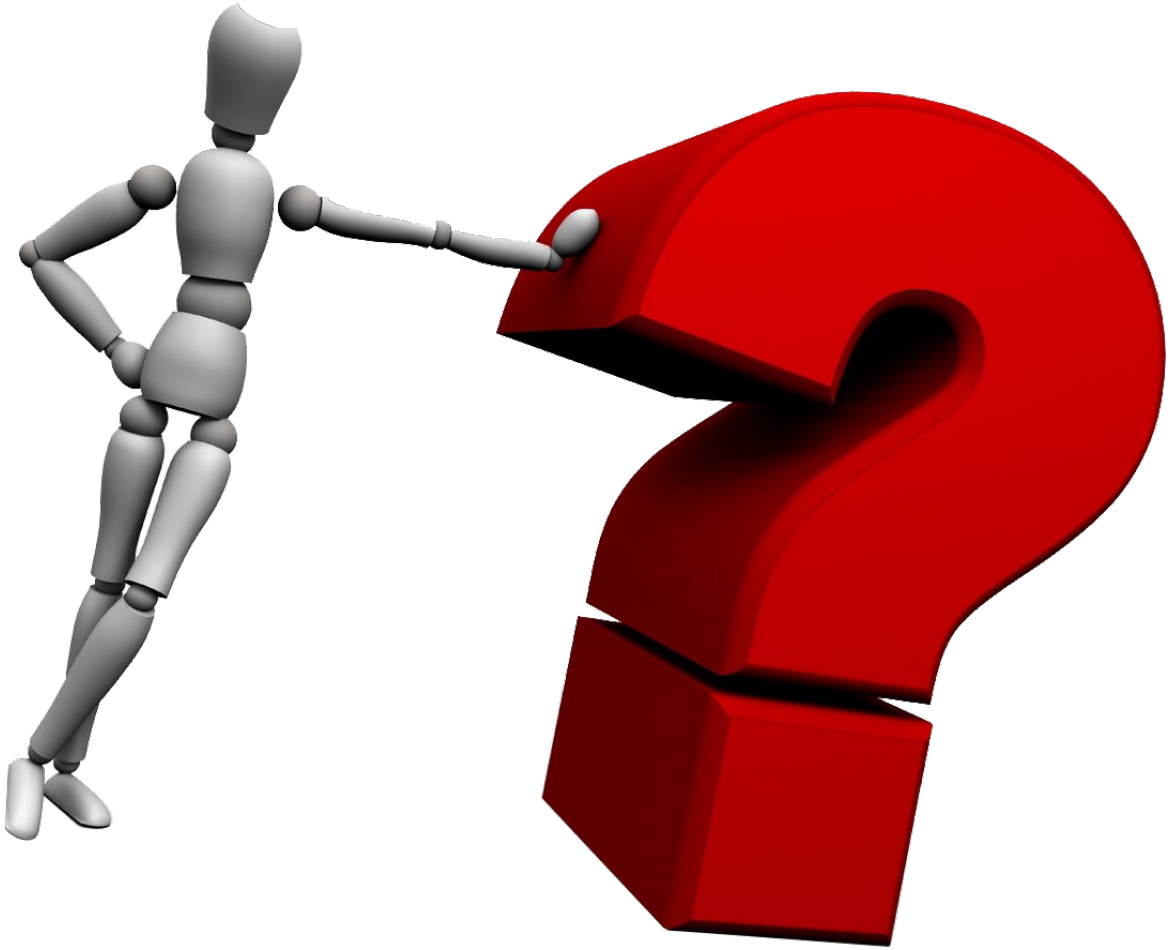
ADD EVENTS FOLDER

- Select "+ New Event" option available on top of the subject identification form
- Add New events from the list based on the criteria.
  - When liver Stopping criteria – Add 'Liver event'
  - When Cardiovascular Events– Add 'Cardiovascular events' \
  - At unscheduled visits e.g., when Lab test performed locally– Add 'Unscheduled





Questions?



BREAKOUT SESSIONS

- Site staff attendees will breakout based on their role
- Physicians will head to: **Heritage C**
- Study Coordinators and Pharmacists will head to: **General Session Room Heritage A/B**
- Please head to that breakout room after the break

GSK × ViiV Healthcare

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LUNCH

GSK × ViiV Healthcare

embrace

BREAK

GSK × ViiV Healthcare

embrace

SUBJECT VISIT WALKTHROUGH

Viviana Wilches

Study Delivery Lead

PRE-SCREENING ACTIVITIES

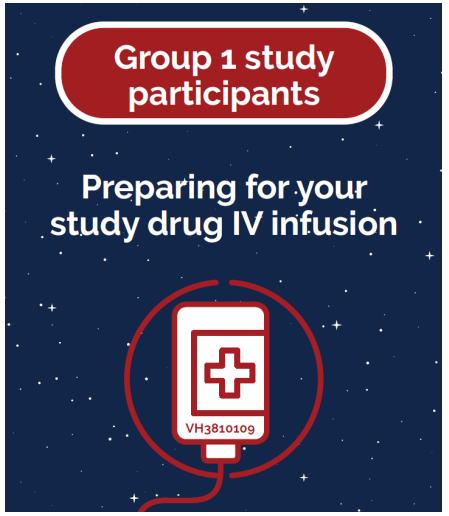
- Create a recruitment plan with your monitor

- Reviewing your patient pool for potential participants who you feel may be interested in the study and meet eligibility criteria
  - Focus on diversity targets – 25% female; 25% non-Caucasian; non-Hispanic
  - Aim to screen and enroll the first patient from these diverse groups

SUPPORTING MATERIAL

Patient and Site Recruitment Material:

Interactive Welcome Guide
Study Website
Study Welcome Guide
Informed Consent Flipchart
Appointment Reminder Cards
Swipeable Stories - IV Infusion arm
Swipeable Stories – SC Infusion arm
Swipeable Stories – SOC arm
Recruitment Flyer
Patient Letter
Recruitment Poster



SCREENING PERIOD – UP TO 75 DAYS

Procedures

- Informed consent
- Eligibility verification
- Demography[1]
- Prior ARV history
- Medical history
- CV risk assessment
- Height, weight (W) and BMI
- Vital signs
- Physical exam (Full)
- CDC HIV-1 Classification
- HIV-associated conditions
- Concomitant Medications
- Adverse event (AE) / SAE assessments
- ECG: triplicate reading

Laboratory Assessments

- Quantitative plasma HIV-1 RNA
- T-cell Lymphocyte subset
- Plasma back-up sample for storage[3]
- Clinical Chemistry
- Hematology
- PT/PTT/INR
- Fasting Lipids and glucose
- Urinalysis
- Pregnancy test for POCBP only (Serum)
- HBsAg, anti-HBc, Anti-HBs, and reflex HBV DNA
- HCV antibody and reflex HCV RNA
- Rapid Plasma Reagin (RPR)
- Whole blood (PBMC)[6]
- COVID-19 testing[9]

Patient Reported Outcomes

- Columbia Suicidality Severity Rating Scale (C-SSRS)

Study Treatment

- IVRS/IWRS[15]

- Visit will last approximately 2 hours
- Demography: Sex at birth, sex at study entry, current gender, race, ethnicity, duration of HIV therapy, time since HIV diagnosis and CD4+ cell count nadir will be collected
- Blood Samples: subject must be fasting
- PBMC samples must be shipped on day of collection at room temperature
- COVID-19 testing: PCR or antigen by the central lab
- C-SSRS: Physician administered evaluation through the IQVIA SCRIBE Portal on the laptop provided
  - **All site staff must be certified in completing the C-SSRS** URL link: https://cssrs.columbia.edu/training/training-options/ **AND** complete the myLesson module before conducting the evaluation
- The screening visit is the same for all three arms of the study
- Enter the subject into RAMOS - IWRS

INCLUSIONARY/EXCLUSIONARY CRITERIA

INCLUSION CRITERIA (SECTION 5.1):

- Participant must be 18 to 70 years of age inclusive, at the time of signing the informed consent.
- Must be on uninterrupted current regimen (either the initial or second ARV regimen) for at least 6 months prior to Screening. Documented evidence of at least two plasma HIV-1 RNA measurements <50 c/mL in the 12 months prior to Screening: one within the 6 to 12-month window, and one within 6 months prior to Screening;
- Plasma HIV-1 RNA <50 c/mL
- Screening CD4+ T-cell count ≥350 cells/mm^3
- Body weight >=50 kg to <=115 kg.
- QTc Interval <450 msec.
- Viral phenotypic sensitivity to VH3810109 based on IC90 of ≤2 µg/mL and a Maximum Percent Inhibition >98% using the Monogram *PhenoSense* mAb Assay

EXCLUSION CRITERIA (SECTION 5.2):

- Medical conditions**:** pregnant, skin disease or disorder, gluteal enhancements, history of cirrhosis; chronic Hep B; Hep C co-infection
- Untreated Syphilis with no treatment documentation; participants who are at least 7 days post completed treatment are eligible or can be re-screened
- Prior receipt of HIV monoclonal antibody
- Stage 3 disease (as per CDC definitions)
- Enrolled in a prior or concurant clinical study that includes drug intervention within the last 30 days
- Previous exposure to cabotegravir

ELIGIBLE SUBJECTS

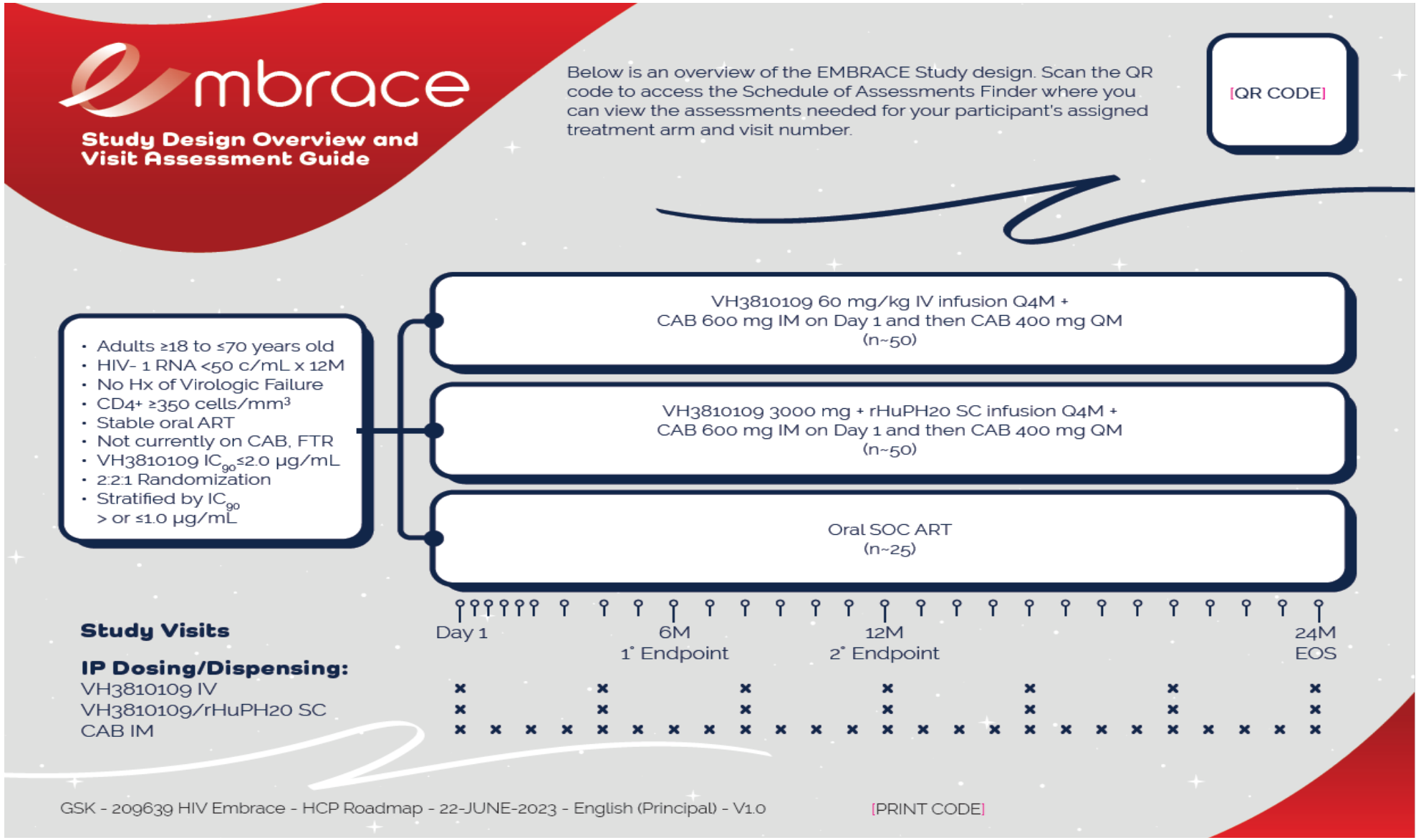
Randomization:

- Enter the RAMOS-IWRS and confirm subject eligibility
  - Stratification will be asked based on the PhenoSense report generated by Monogram
  - The system will assign the study arm the subject is enrolled into
  - A randomization number will be provided and must be entered into the eCRF

- If IP will be dispensed, IP preparation will happen according to the Pharmacy Manual instructions for that specific arm
  - Work with your pharmacist to time the preparation of IP considering the time the patient will arrive
  - NOTE: VH3810109 dosing solutions may be stored at room temperature for up to 4 hours. This includes reconstitution of lyophilized DP, dilution, and storage of the dosing solution in the administration container prior to infusion. Do not shake or freeze the prepared VH3810109 dosing solutions.
  - CAB loading dose will be administered which is 1.5 vials

- In preparation for the study visit and assessments, site staff may review the Schedule of Assessments on the study website

STUDY DESIGN OVERVIEW – INTERACTIVE ROADMAP



embrace

Schedule of Assessments

What study arm is the participant in?

VH3810109 IV Q4M + CAB IM QM	VH3810109 + RHUPH20 SC Q4M + CAB IM QM	STANDARD OF CARE

VH3810109 IV Q4M + CAB IM QM

Which visit is it?

SCREENING	DAY 1	WEEK 1	WEEK 2
MONTH 1	WEEK 6	MONTH 2	MONTH 3
MONTH 4	MONTH 5	MONTH 6	MONTH 7

VH3810109 + rHuPH20 SC Q4M + CAB IM QM

Which visit is it?

SCREENING	DAY 1	WEEK 1	WEEK 2
MONTH 1	WEEK 6	MONTH 2	MONTH 3
MONTH 4	MONTH 5	MONTH 6	MONTH 7

Standard of Care

Which visit is it?

SCREENING	DAY 1	WEEK 1	WEEK 2
MONTH 1	WEEK 6	MONTH 2	MONTH 3
MONTH 4	MONTH 5	MONTH 6	MONTH 7

DAY 1 (BASELINE) – BOTH SC AND IV DOSING ARMS

Procedures

- Eligibility verification
- CV risk assessment
- Height, weight (W) and BMI
- Vital signs
- Physical exam (Targeted)
- CDC HIV-1 Classification
- HIV-associated conditions
- Concomitant Medications
- Adverse event (AE)/ SAE assessments
- ISR assessment
- ECG: triplicate reading

Laboratory Assessments

- Quantitative plasma HIV-1 RNA
- T-cell Lymphocyte subset
- Plasma back-up sample for storage[2]
- Whole Blood[4]
- Clinical Chemistry
- Hematology
- Fasting Lipids and glucose
- Urinalysis
- Pregnancy test for POCBP only (Urine)
- Whole blood (PBMC) (X5)
- COVID-19 testing[9]
- Pharmacokinetics sample
- Optional genetics sample[10]
- Anti-drug antibody (ADA)
- Plasma for exploratory biomarker analyses[11]
- Serum for exploratory biomarker analyses[12]

Patient Reported Outcomes

- Columbia Suicidality Severity Rating Scale (C-SSRS)
- Acceptability of treatment (ACCEPT)
- ISR Diary Card (14 day)
- Perception of Injection (PIN)
- Numeric Rating Scale
- HIVTSQ (status)
- EQ-5D 3L

Study Treatment

- Randomization
- IVRS/IWRS14
- VH3810109 IV infusion
- Cabotegravir Load IM injection

- Visit will last approximately 3-4 hours
- ePROS:
  - ACCEPT; HIVTSQsEQ-5D 3L ; C-SSRS (administered **BEFORE** IP administration
  - PIN; Numeric Rating Scale (administered **AFTER** IP administration
  - ISR is answered every day for 14 days post infusion
  - Capture weight as per protocol guidelines and enter in to the eCRF in kilograms to one decimal place
- Fasting lipids and glucose
- PBMC samples to be shipped the same day they are collected at room temperature
- Cabotegravir load IM injection 1.5 vials used

DAY 1 (BASELINE) – STANDARD OF CARE

Procedures

- Eligibility verification
- Height, weight (W) and BMI
- Vital signs
- Physical exam (Targeted)
- CDC HIV-1 Classification
- HIV-associated conditions
- Concomitant Medications
- Adverse event (AE) / SAE assessments
- ECG: triplicate reading

Laboratory Assessments

- Quantitative plasma HIV-1 RNA
- T-cell Lymphocyte subset
- Plasma back-up sample for storage[3]
- Whole Blood[5]
- Clinical Chemistry
- Hematology
- Fasting Lipids and glucose
- Urinalysis
- Pregnancy test for POCBP only (Urine)
- Whole blood (PBMC)[6]
- COVID-19 testing[9]
- Optional genetics sample[10]

Patient Reported Outcomes

- Columbia Suicidality Severity Rating Scale (C-SSRS)
- Acceptability of treatment (ACCEPT)
- HIVTSQ (status)
- EQ-5D 3L

Study Treatment

- Randomization
- IVRS/IWRS[12]
- SOC ART dispensation

- Capture weight as per protocol guidelines and enter in to the eCRF in kilograms to one decimal place
- ECG – triplicate
- Fasting Lipids and Glucose
- PBMC samples to be shipped the same day they are collected at room temperature
- ePRO administration can happen at any time during the visit
- No dispensing of IP from RAMOS – subject will continue on current ART and a prescription will be filled if required
- No further entry into RAMOS will be required for these participants

WEEK 1 – BOTH DOSING ARMS

Procedures

- ✓ Physical exam (Targeted)
- ✓ HIV-associated conditions
- ✓ Concomitant Medications
- ✓ Adverse event (AE) / SAE assessments
- ✓ ECG: single reading
- ✓ ISR assessment

Laboratory Assessments

- ✓ Quantitative plasma HIV-1 RNA
- ✓ T-cell Lymphocyte subset
- ✓ Plasma back-up sample for storage[2]
- ✓ Plasma for storage for resistance testing[3]
- ✓ Clinical Chemistry
- ✓ Hematology
- ✓ Serum for exploratory biomarker analyses[12]

Patient Reported Outcomes

- ✓ Implementation Science Questionnaire

Study Treatment

- ⊗ None

- ePROS:
  - Implementation Science Questionnaire on their phone
  - Instruct subjects to continue completing the ISR questionnaire every day for 14 days post infusion
- NOTE: NO IP dispensed/administered

WEEK 1 – STANDARD OF CARE

Procedures

- ✓ Physical exam (Targeted)
- ✓ HIV-associated conditions
- ✓ Concomitant Medications
- ✓ Adverse event (AE) / SAE assessments
- ✓ ECG: single reading

Laboratory Assessments

- ✓ Quantitative plasma HIV-1 RNA
- ✓ T-cell Lymphocyte subset
- ✓ Plasma back-up sample for storage[3]
- ✓ Plasma for storage for resistance testing[4]
- ✓ Clinical Chemistry
- ✓ Hematology

Patient Reported Outcomes

- ⊗ None

Study Treatment

- ⊗ None

- No dispensing of IP from RAMOS
- No further entry into RAMOS will be required for these participants

WEEK 2 – BOTH DOSING ARMS

Procedures

- Physical exam (Targeted)
- HIV-associated conditions
- Concomitant Medications
- Adverse event (AE) / SAE assessments
- ISR assessment
- ECG: single reading

Laboratory Assessments

- Quantitative plasma HIV-1 RNA
- T-cell Lymphocyte subset
- Plasma back-up sample for storage[2]
- Plasma for storage for resistance testing[3]
- Clinical Chemistry
- Hematology
- Whole blood (PBMC)
- Pharmacokinetics sample
- Anti-drug antibody (ADA)
- Plasma for exploratory biomarker analyses[11]
- Serum for exploratory biomarker analyses[12]

Patient Reported Outcomes

- None

- ePROS:
  - Confirm subject completed all 14 days of ISR questionnaire
  - NOTE: NO IP dispensed/administered

Study Treatment

- None

WEEK 2 – STANDARD OF CARE

Procedures

- ✓ Physical exam (Targeted)
- ✓ HIV-associated conditions
- ✓ Concomitant Medications
- ✓ Adverse event (AE) / SAE assessments
- ✓ ECG: single reading

Laboratory Assessments

- ✓ Quantitative plasma HIV-1 RNA
- ✓ T-cell Lymphocyte subset
- ✓ Plasma back-up sample for storage[3]
- ✓ Plasma for storage for resistance testing[4]
- ✓ Clinical Chemistry
- ✓ Hematology
- ✓ Whole blood (PBMC)[7]

Patient Reported Outcomes

- ⊗ None

Study Treatment

- ⊗ None

MONTH 1 – BOTH DOSING ARMS

Procedures

- Physical exam (Targeted)
- HIV-associated conditions
- Concomitant Medications
- Adverse event (AE) / SAE assessments
- ISR assessment
- ECG: single reading

Laboratory Assessments

- Quantitative plasma HIV-1 RNA
- T-cell Lymphocyte subset
- Plasma back-up sample for storage[2]
- Plasma for storage for resistance testing[3]
- Clinical Chemistry
- Hematology
- Pregnancy test for POCBP only (Urine)
- Whole blood (PBMC)
- Pharmacokinetics sample
- Anti-drug antibody (ADA)
- Plasma for exploratory biomarker analyses[11]
- Serum for exploratory biomarker analyses[12]

Patient Reported Outcomes

- Columbia Suicidality Severity Rating Scale (C-SSRS)

Study Treatment

- IVRS/IWRS
- Cabotegravir IM injection

- Cabotegravir IM Injection ONLY
- PBMC samples to be shipped the same day they are collected at room temperature

MONTH 1 – STANDARD OF CARE

Procedures

- Physical exam (Targeted)
- HIV-associated conditions
- Concomitant Medications
- Adverse event (AE) / SAE assessments

Laboratory Assessments

- Quantitative plasma HIV-1 RNA
- T-cell Lymphocyte subset
- Plasma back-up sample for storage[3]
- Plasma for storage for resistance testing[4]
- Clinical Chemistry
- Hematology
- Pregnancy test for POCBP only (Urine)
- Whole blood (PBMC)[8]

Patient Reported Outcomes

- Columbia Suicidality Severity Rating Scale (C-SSRS)

Study Treatment

- IVRS/IWRS[12]
- SOC ART dispensation

- No dispensing of IP from RAMOS – subject will continue on current ART and a prescription will be filled if required
- No further entry into RAMOS will be required for these participants

MONTH 1 + 2 WEEKS – BOTH DOSING ARMS

Procedures

- Physical exam (Targeted)
- HIV-associated conditions
- Concomitant Medications
- Adverse event (AE) / SAE assessments
- ISR assessment

Laboratory Assessments

- Quantitative plasma HIV-1 RNA
- T-cell Lymphocyte subset
- Plasma back-up sample for storage[2]
- Plasma for storage for resistance testing[3]
- Clinical Chemistry
- Hematology
- Pharmacokinetics sample

Patient Reported Outcomes

- None

Study Treatment

- None

MONTH 1 + 2 WEEKS – STANDARD OF CARE

Procedures

- Physical exam (Targeted)
- HIV-associated conditions
- Concomitant Medications
- Adverse event (AE) / SAE assessments

Laboratory Assessments

- Quantitative plasma HIV-1 RNA
- Plasma back-up sample for storage[3]
- Plasma for storage for resistance testing[4]
- Clinical Chemistry
- Hematology

Patient Reported Outcomes

- None

Study Treatment

- None

MONTH 2 & 3 – BOTH DOSING ARMS

Procedures

- Physical exam (Targeted)
- HIV-associated conditions
- Concomitant Medications
- Adverse event (AE) / SAE assessments
- ISR assessment

Laboratory Assessments

- Quantitative plasma HIV-1 RNA
- T-cell Lymphocyte subset
- Plasma back-up sample for storage[2]
- Plasma for storage for resistance testing[3]
- Clinical Chemistry
- Hematology
- Pregnancy test for POCBP only (Urine)
- Pharmacokinetics sample
- Anti-drug antibody (ADA)
- Plasma for exploratory biomarker analyses[11]
- Serum for exploratory biomarker analyses[12]

Patient Reported Outcomes

- Columbia Suicidality Severity Rating Scale (C-SSRS)

Study Treatment

- IVRS/IWRS
- Cabotegravir IM injection

- Cabotegravir IM Injection ONLY
- T-cell Lymphocyte subset – MONTH 2 ONLY

MONTH 2 & 3 – STANDARD OF CARE

Procedures

- Physical exam (Targeted)
- HIV-associated conditions
- Concomitant Medications
- Adverse event (AE) / SAE assessments

Laboratory Assessments

- Quantitative plasma HIV-1 RNA
- T-cell Lymphocyte subset
- Plasma back-up sample for storage[3]
- Plasma for storage for resistance testing[4]
- Clinical Chemistry
- Hematology
- Pregnancy test for POCBP only (Urine)

Patient Reported Outcomes

- Columbia Suicidality Severity Rating Scale (C-SSRS)

Study Treatment

- IVRS/IWRS[12]
- SOC ART dispensation

- No dispensing of IP from RAMOS – subject will continue on current ART and a prescription will be filled if required
- No further entry into RAMOS will be required for these participants

MONTH 4 – BOTH DOSING ARMS

Procedures

- Physical exam (Targeted)
- HIV-associated conditions
- Concomitant Medications
- Adverse event (AE) / SAE assessments
- ISR assessment

Laboratory Assessments

- Quantitative plasma HIV-1 RNA
- T-cell Lymphocyte subset
- Plasma back-up sample for storage[2]
- Plasma for storage for resistance testing[3]
- Clinical Chemistry
- Hematology
- Pregnancy test for POCBP only (Urine)
- Whole blood (PBMC)
- Pharmacokinetics sample
- Anti-drug antibody (ADA)
- Plasma for exploratory biomarker analyses[11]
- Serum for exploratory biomarker analyses[12]

Patient Reported Outcomes

- Columbia Suicidality Severity Rating Scale (C-SSRS)
- Acceptability of treatment (ACCEPT)
- ISR Diary Card (14 day)
- Numeric Rating Scale

Study Treatment

- IVRS/IWRS
- VH3810109 IV infusion
- Cabotegravir IM injection

- Coordinate with Pharmacist on IP preparation timing
- ePROS:
  - ACCEPT administered **BEFORE** IP
  - Pain Numeric Scale administered **AFTER** IP
  - ISR is answered every day for 14 days post infusion
- PBMC samples to be shipped the same day they are collected at room temperature

MONTH 5 – BOTH DOSING ARMS

Procedures

- Physical exam (Targeted)
- HIV-associated conditions
- Concomitant Medications
- Adverse event (AE) / SAE assessments
- ISR assessment

Laboratory Assessments

- Quantitative plasma HIV-1 RNA
- T-cell Lymphocyte subset
- Plasma back-up sample for storage[2]
- Plasma for storage for resistance testing[3]
- Clinical Chemistry
- Hematology
- Pregnancy test for POCBP only (Urine)

Patient Reported Outcomes

- Columbia Suicidality Severity Rating Scale (C-SSRS)

Study Treatment

- IVRS/IWRS
- Cabotegravir IM injection

- Cabotegravir IM Injection ONLY

MONTH 4 & 5 – STANDARD OF CARE

Procedures

- Physical exam (Targeted)
- HIV-associated conditions
- Concomitant Medications
- Adverse event (AE) / SAE assessments

Laboratory Assessments

- Quantitative plasma HIV-1 RNA
- T-cell Lymphocyte subset
- Plasma back-up sample for storage[3]
- Plasma for storage for resistance testing[4]
- Clinical Chemistry
- Hematology
- Pregnancy test for POCBP only (Urine)

Patient Reported Outcomes

- Columbia Suicidality Severity Rating Scale (C-SSRS)
- Acceptability of treatment (ACCEPT)

Study Treatment

- IVRS/IWRS[12]
- SOC ART dispensation

- No dispensing of IP from RAMOS – subject will continue on current ART and a prescription will be filled if required
- No further entry into RAMOS will be required for these participants

MONTH 6 – BOTH DOSING ARMS

Procedures

- Height, weight (W) and BMI
- Vital signs
- Physical exam (Targeted)
- HIV-associated conditions
- Concomitant Medications
- Adverse event (AE) / SAE assessments
- ECG: single reading
- ISR assessment

Laboratory Assessments

- Quantitative plasma HIV-1 RNA
- T-cell Lymphocyte subset
- Plasma back-up sample for storage[2]
- Plasma for storage for resistance testing[3]
- Clinical Chemistry
- Hematology
- Fasting Lipids and glucose
- Urinalysis
- Pregnancy test for POCBP only (Urine)
- Whole blood (PBMC)[2]
- Pharmacokinetics sample
- Anti-drug antibody (ADA)
- Plasma for exploratory biomarker analyses[11]

Patient Reported Outcomes

- Columbia Suicidality Severity Rating Scale (C-SSRS)
- Acceptability of treatment (ACCEPT)
- Perception of Injection (PIN)
- HIVTSQ (status)
- HIVTSQ (change)
- EQ-5D 3L
- Imp. Sci. Questionnaire
- Participant Interviews

Study Treatment

- IVRS/IWRS
- Cabotegravir IM injection

- ePROS:
  - ACCEPT; HIVTSQs, HIVTSQc, EQ-5D 3L ; C-SSRS (administered **BEFORE** IP administration
  - PIN and Implementation Science Questionnaire administered **AFTER** IP administration
- Capture weight as per protocol guidelines and enter in to the eCRF in kilograms to one decimal place
- ECG – triplicate
- Implementation Science Interview of a subset of participants – will occur within 4 weeks of M6 completion
- PBMC samples to be shipped the same day they are collected at room temperature

MONTH 6 – STANDARD OF CARE

Procedures

- Height, weight (W) and BMI
- Vital signs
- Physical exam (Targeted)
- HIV-associated conditions
- Concomitant Medications
- Adverse event (AE) / SAE assessments
- ECG: single reading

Laboratory Assessments

- Quantitative plasma HIV-1 RNA
- T-cell Lymphocyte subset
- Plasma back-up sample for storage[3]
- Plasma for storage for resistance testing[4]
- Clinical Chemistry
- Hematology
- Fasting Lipids and glucose
- Urinalysis
- Pregnancy test for POCBP only (Urine)
- Whole blood (PBMC)[7]

Patient Reported Outcomes

- Columbia Suicidality Severity Rating Scale (C-SSRS)
- Acceptability of treatment (ACCEPT)
- HIVTSQ (status)
- HIVTSQ (change)
- EQ-5D 3L

Study Treatment

- IVRS/IWRS[12]
- SOC ART dispensation

- No dispensing of IP from RAMOS – subject will continue on current ART and a prescription will be filled if required
- No further entry into RAMOS will be required for these participants

MONTH 7, 9, 11, 13, 15, 17, 19, 21, 23 – BOTH DOSING ARMS

Procedures

- Physical exam (Targeted)
- HIV-associated conditions
- Concomitant Medications
- Adverse event (AE) / SAE assessments
- ISR assessment

Laboratory Assessments

- Quantitative plasma HIV-1 RNA
- T-cell Lymphocyte subset
- Plasma back-up sample for storage[2]
- Plasma for storage for resistance testing[3]
- Clinical Chemistry
- Pregnancy test for POCBP only (Urine)

Patient Reported Outcomes

- Columbia Suicidality Severity Rating Scale (C-SSRS)

Study Treatment

- IVRS/IWRS
- Cabotegravir IM injection

- Cabotegravir IM Injection ONLY

MONTH 7, 9, 11, 13, 15, 17, 19, 21, 23 – STANDARD OF CARE

Procedures

- Physical exam (Targeted)
- HIV-associated conditions
- Concomitant Medications
- Adverse event (AE) / SAE assessments

Laboratory Assessments

- Quantitative plasma HIV-1 RNA
- Plasma back-up sample for storage[3]
- Plasma for storage for resistance testing[4]
- Pregnancy test for POCBP only (Urine)

Patient Reported Outcomes

- Columbia Suicidality Severity Rating Scale (C-SSRS)

Study Treatment

- IVRS/IWRS[12]
- SOC ART dispensation

MONTH 8 & 12 – BOTH DOSING ARMS

Procedures

- Height, weight (W) and BMI
- Vital signs
- Physical exam (Targeted)
- HIV-associated conditions
- Concomitant Medications
- Adverse event (AE) / SAE assessments
- ISR assessment
- ECG: single reading

Laboratory Assessments

- Quantitative plasma HIV-1 RNA
- T-cell Lymphocyte subset
- Plasma back-up sample for storage[2]
- Plasma for storage for resistance testing[3]
- Clinical Chemistry
- Hematology
- Pregnancy test for POCBP only (Urine)
- Whole blood (PBMC)[9]
- Pharmacokinetics sample
- Anti-drug antibody (ADA)
- Plasma for exploratory biomarker analyses[11]
- Serum for exploratory biomarker analyses[12]

Patient Reported Outcomes

- Columbia Suicidality Severity Rating Scale (C-SSRS)
- Acceptability of treatment (ACCEPT)
- Numeric Rating Scale
- Perception of Injection (PIN)

Study Treatment

- IVRS/IWRS
- VH3810109 IV infusion
- Cabotegravir IM injection

- ePROS:
  - ACCEPT administered **BEFORE** IP
  - PIN & Pain Numeric Scale administered **AFTER** IP
- PBMC samples to be shipped the same day they are collected at room temperature

MONTH 8 & 12 – STANDARD OF CARE

Procedures

- Height, weight (W) and BMI
- Vital signs
- Physical exam (Targeted)
- HIV-associated conditions
- Concomitant Medications
- Adverse event (AE) / SAE assessments

Laboratory Assessments

- Quantitative plasma HIV-1 RNA
- T-cell Lymphocyte subset
- Plasma back-up sample for storage[3]
- Plasma for storage for resistance testing[4]
- Clinical Chemistry
- Hematology
- Pregnancy test for POCBP only (Urine)
- Whole blood (PBMC)[6]

Patient Reported Outcomes

- Columbia Suicidality Severity Rating Scale (C-SSRS)
- Acceptability of treatment (ACCEPT)

Study Treatment

- IVRS/IWRS[12]
- SOC ART dispensation

MONTHS 10, 14, 18, 22 – BOTH DOSING ARMS

Procedures

- Physical exam (Targeted)
- HIV-associated conditions
- Concomitant Medications
- Adverse event (AE) / SAE assessments
- ISR assessment

Laboratory Assessments

- Quantitative plasma HIV-1 RNA
- Plasma back-up sample for storage[2]
- Plasma for storage for resistance testing[3]
- Clinical Chemistry
- Hematology
- Pregnancy test for POCBP only (Urine)

Patient Reported Outcomes

- Columbia Suicidality Severity Rating Scale (C-SSRS)

- Cabotegravir IM Injection ONLY

Study Treatment

- IVRS/IWRS
- Cabotegravir IM injection

MONTHS 10, 14, 18, 22 – STANDARD OF CARE

Procedures

- Physical exam (Targeted)
- HIV-associated conditions
- Concomitant Medications
- Adverse event (AE) / SAE assessments

Laboratory Assessments

- Quantitative plasma HIV-1 RNA
- Plasma back-up sample for storage[3]
- Plasma for storage for resistance testing[4]
- Clinical Chemistry
- Hematology
- Pregnancy test for POCBP only (Urine)

Patient Reported Outcomes

- Columbia Suicidality Severity Rating Scale (C-SSRS)

Study Treatment

- IVRS/IWRS[12]
- SOC ART dispensation

MONTHS 16 & 20 – BOTH DOSING ARMS

Procedures

- Physical exam (Targeted)
- HIV-associated conditions
- Concomitant Medications
- Adverse event (AE) / SAE assessments
- ISR assessment

Laboratory Assessments

- Quantitative plasma HIV-1 RNA
- T-cell Lymphocyte subset
- Plasma back-up sample for storage[2]
- Plasma for storage for resistance testing[3]
- Clinical Chemistry
- Hematology
- Pregnancy test for POCBP only (Urine)
- Whole blood (PBMC)[9]
- Pharmacokinetics sample
- Anti-drug antibody (ADA)
- Plasma for exploratory biomarker analyses[11]
- Serum for exploratory biomarker analyses[12]

Patient Reported Outcomes

- Columbia Suicidality Severity Rating Scale (C-SSRS)

Study Treatment

- IVRS/IWRS
- VH3810109 IV infusion
- Cabotegravir IM injection

- PBMC samples to be shipped the same day they are collected at room temperature

MONTHS 16 & 20 – STANDARD OF CARE

Procedures

- Physical exam (Targeted)
- HIV-associated conditions
- Concomitant Medications
- Adverse event (AE) / SAE assessments

Laboratory Assessments

- Quantitative plasma HIV-1 RNA
- T-cell Lymphocyte subset
- Plasma back-up sample for storage[3]
- Plasma for storage for resistance testing[4]
- Clinical Chemistry
- Hematology
- Pregnancy test for POCBP only (Urine)
- Whole blood (PBMC)[6]

Patient Reported Outcomes

- Columbia Suicidality Severity Rating Scale (C-SSRS)

Study Treatment

- IVRS/IWRS[12]
- SOC ART dispensation

MONTH 24 – BOTH DOSING ARMS

Procedures

- Height, weight (W) and BMI
- Vital signs
- Physical exam (Targeted)
- HIV-associated conditions
- Concomitant Medications
- Adverse event (AE) / SAE assessments
- ISR assessment
- ECG: single reading

Laboratory Assessments

- Quantitative plasma HIV-1 RNA
- T-cell Lymphocyte subset
- Plasma back-up sample for storage[2]
- Plasma for storage for resistance testing[3]
- Clinical Chemistry
- Hematology
- Fasting Lipids and glucose
- Urinalysis
- Pregnancy test for POCBP only (Urine)
- Whole blood (PBMC)[9]
- Pharmacokinetics sample
- Anti-drug antibody (ADA)
- Plasma for exploratory biomarker analyses[11]
- Serum for exploratory biomarker analyses[12]

Patient Reported Outcomes

- Columbia Suicidality Severity Rating Scale (C-SSRS)
- Acceptability of treatment (ACCEPT)
- Perception of Injection (PIN)
- Numeric Rating Scale
- HIVTSQ (status)
- EQ-5D 3L

Study Treatment

- IVRS/IWRS
- VH3810109 IV infusion
- Cabotegravir IM injection

- ePROS:
  - ACCEPT; HIVTSQs, EQ-5D 3L ; C-SSRS (administered **BEFORE** IP administration
  - PIN and Numeric Rating Scale administered **AFTER** IP administration
- Capture weight as per protocol guidelines and enter in to the eCRF in kilograms to one decimal place
- PBMC samples to be shipped the same day they are collected at room temperature

MONTHS 24 – STANDARD OF CARE

Procedures

- Height, weight (W) and BMI
- Vital signs
- Physical exam (Targeted)
- HIV-associated conditions
- Concomitant Medications
- Adverse event (AE) / SAE assessments
- ECG: single reading

Laboratory Assessments

- Quantitative plasma HIV-1 RNA
- T-cell Lymphocyte subset
- Plasma back-up sample for storage[3]
- Plasma for storage for resistance testing[4]
- Clinical Chemistry
- Hematology
- Fasting Lipids and glucose
- Urinalysis
- Pregnancy test for POCBP only (Urine)
- Whole blood (PBMC)[6]

Patient Reported Outcomes

- Columbia Suicidality Severity Rating Scale (C-SSRS)
- Acceptability of treatment (ACCEPT)
- HIVTSQ (status)
- EQ-5D 3L

Study Treatment

- IVRS/IWRS[12]

END OF STUDY – MONTH 24

Participants in the Dosing Arms:

A participant is considered to have completed the main study if the participant has completed all phases of the study up to and including the Month 24 visit

If a participant chooses to enter the Continued Access Phase of the study, in which case the participant is considered to have completed the study as of their last visit/ follow-up in the Continued Access Phase, per the SoA.

The Continued Access Phase will be a monthly visit and will follow the same dosing schedule as in the main study (ie. Monthly CAB dosing and VHVH3810109 IV infusion OR SC Infusion every 4 months)

Participants in the SOC Arm:

All SOC participants will complete the study at Month 24

GSK × ViiV Healthcare

embrace

STUDY TIMELINES & WHAT IS NEXT

Christine Nase

Local Delivery Lead

STUDY TIMELINES

• First Center Initiated	07-August-2023
• First Subject First Visit	10-August-2023
• First Subject First Dose	09-Oct-2023
• Last Subject Screened	19-Jan-2024
• Last Subject Enrolled	16-Feb-2024
• Last Subject Last Visit	04-Aug-2025

NEXT STEPS- SITE INITIATION

What is needed:

- Contract and budget finalized
- IRB approval for study along with any patient facing documents (ICFs, advertisement, patient ID card, etc.) Note there are four consent forms:

1. Model/Main ICF
2. Optional Genetics
3. Pregnant Participant
4. Restart ICF

- Site training modules complete
- GSK receipt of regulatory documents (1572, CVs, FDFs)
- Protocol signature page

NEXT STEPS- SITE INITIATION (CONT.)

Your site will receive the following for utilization during the study:

- Q2: Lab Kits
- IQVIA: one tablet (for questionnaire) and one cell phone (for patients who do not own cell phone – utilized for diary)
- Recruitment Materials
- Thermo Fisher: Syringe Pump if requested
- Thermo Fisher: Dosing Supplies (for five subjects)
  - 60 mL syringe
  - In-line filter infusion set
  - 5 micron filter needle
  - Butterfly needle (21-23 gauge).

EXPECTATIONS THROUGHOUT THE STUDY

- Recruitment plan will be reviewed at every visit
- Enrollment log will be shared with you at the SIV and expectation is to send to Christine the first and third Friday of each month (Christine.m.nase@gsk.com).
- CRA will need to visit your site within 7-`10 business days of when your first subject is enrolled/dosed. Please accommodate this request.
- CRAs should assess the need for Monitoring Visits and schedule their visits based on the site's enrolment activity, performance, quality, and study milestones using available tools and information. Please ensure that the CRA has access to the source a quiet space to monitor and staff access as needed
- For invoiceable items, please remember to submit all invoices in a timely manner. (ie: quarterly)

SCHEDULING SIV

Your GSK CRA will contact you when you are almost ready to open (contract/budget close to finalization, IRB approval along with the majority of necessary regulatory documents received)

The SIV visit may be performed remotely or on site. Your visit will be tailored to your needs. For example, review of protocol with those who aren't in attendance today; tour of facility; meeting with pharmacist, etc. Study recruitment planning will be discussed as well.

The primary investigator will need to be available during the SIV to meet with the CRA. The CRA will need to maintain an open line of communication with the PI throughout the study

CENTRAL MAILBOX FOR QUESTIONS

All protocol related questions as well as safety questions are to be sent to the study group mailbox: RD.Embracestudy@gsk.com

US LOCAL TEAM CONTACTS

Note: Your GSK CRA is your initial point of contact.

The US InHouse team includes the following people

• Lisette Enriquez, Study Start Up Coordinator	lisette.2.enriquez@gsk.com	610 917-4644
• Kelsey-Anne Fann, Clinical Study Associate	Kelsey-anne.x.fann@gsk.com	
• Christine Nase, Local Delivery Lead	Christine.m.nase@gsk.com	267 990-2750
• Nicole Washco, Study Start Up Lead	nicole.x.washco@gsk.com	610 917-6957

QUESTIONS