Monitoring Plan Version	2.0	Monitoring Plan Date	04 May 2026
Program	VISWIN	Investigational Product	Vedolizumab
Study Number	Vedolizumab-4071	Protocol Version and Date	Version 1.0 dated 09 Oct 2025
Study Abbreviated Title	Taiwan UC/CD Patients Comparative Effectiveness in Real-World Setting		

Monitoring Plan (ICH-GCP E6 (R2)) – ***A description of the methods, responsibilities and requirements for monitoring the trial.***

This guide serves to provide the basic elements and their expectations of a monitoring plan that should be considered.

The Monitoring Plan should be developed considering that will be tailored to the specific human subject protection and data integrity risks of the trial. The plan should describe the monitoring strategy, the monitoring responsibilities of all parts involved, the various monitoring methods to be used and the rationale for their use. The plan should emphasize the monitoring critical processes. Trial specific elements should also be included if necessary, for plan to be changed, all changes must be documented in a new version.

Particular attention should be given to those aspects that are not routine clinical practice and that require additional training.

The monitoring plan should reference the applicable policies and procedures. The level of monitoring required for the study is risk based and takes into account the risk assessment.

Terminology

Central Monitoring: A remote evaluation carried out by sponsor personnel or representatives (e.g., Data Manager, Statistician, or Monitor).

Off-site Monitoring: Monitoring activities as defined **either within process documents or in the monitoring plan (MP)** that occur away from the study site location (e.g., at a Monitor's home or in a sponsor representative's office). This is also commonly known as **remote monitoring**. It should be done throughout systems available for the study (e.g.: EDC, eTMF, IRT, etc.).

On-site Monitoring: An **in-person evaluation** carried out by sponsor personnel or representative(s) at the site(s) at which the clinical investigation is being conducted.

Source Document Verification (SDV) (Accuracy): Commonly known as '**transcription checking**', the process by which data within the CRF or other data collection systems are compared to the original source of information (and vice versa) to confirm that the data were transcribed accurately (i.e. data from source matches data in the CRF or other system and vice versa). It should be done on-site.

SDR (Quality): Review of source documentation to check **quality of source**, review **protocol compliance, ensure the Critical Processes and source documentation** (e.g. accurate, legible, contemporaneous, original, attributable) are adequate, to ascertain Investigator involvement and appropriate delegation, and assess compliance to other areas (e.g. SOPs, ICH GCPs). SDR is not a comparison of source data against CRF data. It should be done on-site.

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Color	Instruction
Black text	Standard language. Do not remove or alter.
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1. Scope			
Objective	Primary Objective • To characterize the real-world profiles of ulcerative colitis and Crohn's disease under advanced therapy in Taiwan, summarizing baseline characteristics and 1-year outcomes (clinical response and endoscopic remission) after initiation in cycle 1 or cycle 2 across approved biologics and small-molecule agents (anti-TNFα agents, vedolizumab, ustekinumab, upadacitinib, tofacitinib, ozanimod). Within the subgroup who start vedolizumab as their first advanced therapy, we state a single confirmatory hypothesis: early initiation (≤2 years from diagnosis) yields a higher 1-year endoscopic remission rate than non-early initiation (>2 years). Related readouts (1-year clinical response, the four-category joint outcome, and time-to-event measures) will be supportive and interpreted as hypothesis-generating. Secondary Objective • To describe real-world patterns of advanced therapy use under Taiwan's National Health Insurance reimbursement policy, focusing on therapies administered during the first and second treatment cycles, including the treatment gap between cycles, and within disease-by-cycle strata (UC-cycle 1/2 and CD-cycle 1/2), explore comparative effectiveness across advanced therapies on prespecified 1-year outcomes (clinical status, endoscopic remission, steroid-free remission, treatment duration, IBD-related hospitalization and surgery). These secondary analyses are exploratory in intent. Exploratory Objective • To evaluate the impact of treatment timing by comparing patients who initiated their first advanced therapy within 6 months of diagnosis versus those who started later. Outcomes will be assessed through 1-year clinical response categories, survival analyses of time to response and remission, and longitudinal changes in disease activity during follow-up; all findings here will be hypothesis-generating.		
Study Title	A Multi-Centre, Non-Interventional, Retrospective Chart-Review Study: The Real-World Comparative Effectiveness of Ulcerative Colitis and Crohn's Disease Patients with Advanced Treatments and Impact of Treatment Forced Discontinuation in Taiwan		
Phase	Retrospective	**Study Number**	Vedolizumab-4071

	Applicability		The monitoring plan applies to all Clinny Biotech Limited employees who are involved in site management of this study.
	SOP Applicability List		The applicable SOP list will be a stand-alone document in appendix A and updated through the study if required.
2. Clinical Operations Representative (COR) Assignment – The monitoring activities may be done by COR or designee. The study team manager should select a COR or designee. However, it is essential to evaluate the professional minimum requirements as the following:			
	Minimum Requirements	**Monitors experience must be commensurate with the level of the study**	The COR (CRA) should be bachelor's degree or above in science/medical field.
		Proficiency in local language	Traditional Chinese
		Knowledge about local regulations	COR (CRA) should have GCP training certificate more than 8 hour within 1 year according to the local regulation announced on 2024.
	Has a study back up been established?		One project manager and 2 CORs (CRAs) will be assigned from ClinnyBio to this study. CORs (CRAs) can be back up each other and the project manager can also be the deputy when COR (CRA) absent.
	Has the Takeda COPM received and reviewed the assigned candidate CV?		Takeda Senior RWE Evidence Scientist will be taken responsibility of the COPM role in this study. COPM will receive and review the CV of the Clinical Operations Representative assigned to the study.
3. Communication Plan - Communication responsibilities, methods, and cadence must be described in the monitoring plan in clear way and considering the different stakeholders. The study contact list must be a stand-alone document which must be up-to-date every change and must be kept in order to guarantee the traceability of personnel involved throughout the study.			
	3.1 Takeda and Monitoring Vendor Communication:		In this VISWIN study, ClinnyBio representatives are the primary contact for site staff and vendor about related activities. Takeda representatives could be involved when consultation needs, issue escalation and/or as sponsor representative for external contacts. For the resolution of technical questions, study team members should communicate with the ClinnyBio CRM and Takeda Senior RWE Evidence Scientist (COPM) in relevant communications.

		In cases when a Takeda non-core team member needs to communicate with ClinnyBio (e.g. information exchange, request for change in process, request for additional work, etc.) an email to the ClinnyBio representative should be sent. ClinnyBio will provide study status update regularly and meet with Takeda when required. The meeting minutes will be taken by ClinnyBio and sent to Takeda for review and comment. The representatives from each party should forward the meeting information and final meeting minutes to responsible study team members. The meeting minutes will also be filed in TMF for documentation.
	3.2 Site Communications	Sites will be managed by assigned ClinnyBio study team members who will be ultimately responsible for the site communication and issue escalation. ClinnyBio CORs (CRAs) will contact site staff bi-weekly at least during IRB submission and recruitment period. During the study follow-up period, the contact will be performed monthly at least.
	3.3 Other Communications	Generally, in email communication, team members who are responsible for actions should be in the "to" line, team members who receive the email for information should be added to the cc line. All relevant communications (only if the content is not documented in any other manner) is filed in Trial Master File. Relevant communications are generally defined as: Communications that are directly related to the study protocol (e.g. subject eligibility, visit procedures, Adverse Events/Serious Adverse Events), important operational issues (e.g. staff changes), and to the overall conduct of the clinical trial to meet local regulatory and ICH requirements. This should exclude communications related to draft documents, financial matters and exchanges of pleasantries. For emails, the most recent version of the email including all discussion threads should be provided. Previous versions are not required. If an email introduces a topic or begins to address an issue, the remainder of the discussion (i.e. considerations, decisions, actions, and outcomes) should be included in the study master file. Preferably issues are addressed in meeting actions/minutes and study FAQ log even if the introduction was via phone or email. Proper meeting minutes help ensure issues are followed to their conclusion.

		In case that Takeda internal communication is relevant for filing in study master file, the initiator of the correspondence is responsible for filing. Face-to-face or telephone conversations will be summarized and documented. The ClinnyBio study team members involved in the conversation will be responsible for preparing the related e-mail and/or other equivalent documentation, which will be filed in trial master file.	
4. Patient Recruitment and Monitoring Activities: The monitoring plan must establish the foreseen recruitment targets, as described in item 4.1, in order to the COR to be aware.			
	4.1 Initial Planned Dates, Recruitment and Site Initiation Objectives	**Number of countries planned to conduct the study**	1
		Enrollment period duration	Jun 2026 to Feb 2027
		First subject enrolled	Jun 2026
		Last subject enrolled	Feb 2027
		Last subject completed	Feb 2027
		Data base lock	May 2027
		Site Activation	May 2026
		Site Closure and Site Replace Process	Jun 2027
	4.2 Subject Recruitment	Total 1,000 subjects will be enrolled from 6 sites retrospectively. The patient data collection can only be proceeded after IRB approve the study and clinical study agreement with each study site is fully executed.	
	4.3 Site Monitoring Procedures		
	4.3.1 Site Qualification Visit	ClinnyBio Oversight The ClinnyBio project manager will work in parallel with COR, Takeda team COPM, and related Takeda team member to identify sites for a qualification visit (QV). The ClinnyBio project manager is responsible for disseminating the list of sites identified for a QV to the CORs. Site can only be visited when:	

		1. Synopsis is available 2. Questionnaire is approved by Takeda 3. Qualification training materials are available and CORs have been trained. Contracted Scope ClinnyBio will conduct one Qualification Visit/ Call for each approved site at 8 identified sites in Taiwan. It is estimated that 6 sites to be selected in this study. Pre-Visit Communication CORs will contact the site to schedule a date and time that is convenient for the Principal Investigator (PI) to perform the Qualification Visit. The availability of the potential PI during the qualification visit is mandatory and should be confirmed by the COR in advance. COR will send a confirmation letter and agenda to the site at least 2 working days prior the QV via e-mail. A copy of the confirmation letter must be kept in the investigator's file and the TMF per TMF filing instructions. Qualification Activities The COR should collect the following documents during QV: 1. Contact details for site personnel. 2. Confidentiality Agreement signed by PI 3. PI's CV In addition, the activities of on-site qualification visits include: 1. Study synopsis review.

		2. Review of ClinnyBio as CRO roles, responsibilities, and obligations. 3. Principal Investigator experience 4. Discuss about local IRB/IEC requirements and timelines. 5. The COR must go through and discuss the questions listed on Takeda approved questionnaire Follow-up Communication Follow-up communication to the site should be by e-mail. The follow-up e-mails must be written within 10 working days after the last day of the visit. Documentation A Qualification Visit Report documenting the visit will be generated and finalized within 10 working days. Approval of Qualified Sites Sites will be approved by Takeda COPM and the list of approved sites shall be provided to ClinnyBio for further site management. Site Selection Criteria Following the qualification visit, the site must meet the following criteria to be selected for the trial: 1. The site estimates to have at least 80 patients that match the inclusion/ exclusion criteria. 2. The site estimates to be able to collect all eligibility patients' data within 7 to 8 months. 3. The study required data are reachable and accessible, no matter whether from medical record, educational nurse record, and/or other source from study sites. 4. The site has adequate staff processes for patient identification and the required time period is fulfill Takeda expectation.

		5. The site has the ability to be initiated no later than the average expected time after the site is qualified. 6. PI is engaged, suitably qualified, and agrees to the study protocol
	4.3.2 Site Staff Training	Site staff training will be documented in SOP-004-F04 Site Staff - Project Training Log with training topics and training date. The GCP training certificate and CVs will be collected as qualification documents. Medical license should be obtained if medical license number is not listed in investigator's CV.
	4.3.3 Site Initiation Visit	Site Initiation must be according to SOP-004 Site Initiation Visit. - ClinnyBio will conduct the Site Initiation Visit once the regulatory documents are in place. - COR (CRA) will ensure all applicable ethics approvals and supplies are available at the study sites on or before SIV date. - In addition to the activities described in the applicable SOP and in the project specific 'SVR and Issue Guidance Document' (SOP-005-F01), project specific requirements for the conduct of the initiation visit/calls include (but not limited to): ▪ Study Protocol Training ▪ Specific forms related to EDC (e.g. EDC specific training checklist, User Account forms and access) ▪ Review of eCRF Completion Guideline ▪ ICF waiving ▪ SDV process ▪ Safety cases reporting process ▪ GCP Guidelines ▪ Recruitment plan and potential subject number ▪ Ensure the Site Visit Log is signed and dated by all site staff present during the visit. ▪ Review IRB initial approval and subsequent approval ▪ Ensure the Site Staff Delegation Log completed during the visit.

		The COR (CRA) who completes the initiation visit will issue a follow-up letter via e-amil to the site staff within approximately 10 working days after the day of the visit, summarizing items reviewed, issues identified/pending resolution, and addressing any question(s) left outstanding at the visit. A copy of the email should be filed in Trial Master File.	
	4.3.4 Defining the Monitoring The plan should describe the monitoring strategy, the monitoring responsibilities of all the parties involved (e.g.: medical monitoring, data management, clinical supplies, IRT, etc.), the various monitoring methods (central, off-site, and on-site monitoring activities) to be used and their rationale for their use. The rationale for the chosen monitoring strategy should also be described (ICH GCP E6). The plan must also emphasize the monitoring of critical data and processes specific for the study with the intention to reduce risk per ICH GCP E6.	**On-site and off-site Data Monitoring**	On-site Data Monitoring: Medical records, site study team research data, and paper-based worksheets maintained at the investigational sites will be reviewed during on-site data monitoring. The study team research data may be maintained in variable formats and will be reviewed as confirmed by the investigators. Off-site Data Monitoring: It is not applicable for this study.
		Blinding and Unblinding Monitoring Process	NAP
		Critical Data	The critical data of this study include: 1. Key Eligibility Criteria • Diagnosis of UC or CD • The first initiation of any of the advanced therapies on or after 1 Jan 2018. 2. Primary Objective • Characterize the real-world profiles of ulcerative colitis and Crohn's disease under advanced therapy in Taiwan. ○ 1-year outcomes (clinical status and/or endoscopic status) after initiation in cycle 1 or cycle 2 across approved biologics and small-molecule agents ○ Time period between the first diagnosis and the first dose of advanced treatment.

			3. Secondary Objective • Treatment pattern of advanced therapies.
		Critical Processes	The critical processes for corresponding data are listed below: 1. Key Eligibility Criteria • Review and verify key inclusion/exclusion criteria including primary diagnose of UC or CD and the first dose of IBD-related advanced treatment. 2. Primary Objective • Review and verify UC and CD diagnosis information and subject characteristics. 3. Secondary Objective • Review and verify UC and CD related treatment from index date, until end/discontinuation of treatment, and end of study observation period. • Review and verify disease index performed from diagnosis to end of study observation period. COR (CRA) and site training – collection, review, assessment and reporting of safety events (i.e. severity, grade, causality) according to the protocol and local requirements.
		Risk Indicators and Thresholds	Risk Indicators and Thresholds which should be considered are (but not limited to): ○ Potential quality concerns ○ Number of subjects enrolled ○ Numerous outstanding action items ○ Major changes in site staff ○ Numerous changes to CORs (CRAs) assigned to site

			○ Audit findings not resolved in a timely manner. ○ Volume of protocol deviations ○ Backlog of e-Case Report Form
	4.3.4.1 First Monitoring Visit	The first on site monitoring visit will take place within approximately two (2) weeks after the first 10-subject enrolled in the trial.	
		The following data of the first subject will get 100% SDV during the first monitoring visit. - verify that subjects meet inclusion/exclusion criteria - review and verify disease index performed from index date and end of each treatment cycle.	
	4.3.4.2 Interim Monitoring	The on-site monitoring visits will be performed twice during study period. It is estimated to conducted up to 12 visits for this study. The second on-site monitoring visit will be performed after all data collection activities are completed. **Sites will not be visited if no subjects have been enrolled.**	
		Quality Issues/Safety reporting issues, if applicable	Co-monitoring visits will be conducted by ClinnyBio CRM and/or Takeda COPM together with the respective COR (CRA). At a minimum, one co-monitoring visit will be performed during the site initiation visit, and one co-monitoring visit will be conducted during the second routine monitoring visit at each site.
		Clinical Operations Presentative Activities	CORs (CRAs) will perform 10% source document verification (SDV) of all data points for all subjects via on-site monitoring. Where ClinnyBio is contracted to perform on-site monitoring of subject data, 100% SDV of the following points is required for all enrolled subjects: - verify that subject meets inclusion/exclusion criteria

			The rule for 10% SDV should include 100% SDV for critical data listed above and select other new subject data occurred to achieve total 10% SDV rate. The amount of SDV performed for each subject must be clearly stated on the monitoring visit report. Data queries related to Data Points requiring SDV, are also subject to the same level of SDV. Include information here on the SDV strategy for queries raised after the last scheduled monitoring visit to site. Suggested strategies include: - No SDV of queries raised after the last MV to site - Additional MVs required to perform SDV of queries
		Back-log Issues	The study data will be collected within 9 months after the first site initiated according to protocol. If the data entry back-log achieving 30% of the study site, an e-mail will be sent to PI and SC and copy Takeda as reminding. If the data entry back-log achieving 50%, an on-site visit will be triggered under Takeda's approval.
		Study Supplies	NAP
		Biological Sample Management	NAP
		Frequency ISF is checked	The ISF will be reviewed at 2nd monitoring visit at least to ensure the completeness and current. Pending activities will be documented in SVR and Follow-Up Letter.

		Reconciliation of ISF and eTMF	All site-specific documents will be forwarded to the Trial Master File. A final review and reconciliation should be performed during the Termination Visit.
		The Subject Screening & Enrollment Log will be maintained for all enrolled subjects and reviewed by the COR (CRA) during on-site monitoring visits. To ensure the protection of subject confidentiality, the Subject Identification Log will only be accessible for review during on-site visits. The logs described above may be completed using site-specific formats and maintained in typed form.	
	4.3.4.3 Centralized Monitoring (if applicable)	**Document rational in the event centralized monitoring would be adopted for the study. Activities developed must be specific in the monitoring plan to include the following:**	
		How will it be carried out:	NAP
		How will it be reviewed:	NAP
		By whom:	NAP
		How will it be reported:	NAP
		How will it be followed up:	NAP
	4.3.4.4 Off-site Monitoring (Remote Monitoring)	Off-site monitoring is not applicable for this study.	
	4.3.4.5 Close-Out Visit	The site must be closed according to Termination Visit procedure (SOP-007 Termination Visit).	
	4.3.5 Monitoring Visit Report (MVR) and Communication	COR (CRA) should submit the Draft Monitoring Visit Report (MVR) within 5 working days after last day of the visit. ClinnyBio CRM will approach CRAs to obtain PDF versions of the MVR. All MVRs will be 100% reviewed by CRM and CRM will provide the feedback to COR (CRA) via PDF version. Finalization of MVR	

		should be within 10 working days after last day of visit with electronic signatures by both COR (CRA) and CRM and the final signed report will be filed in TMF accordingly. Send Final MVR to Takeda: MVRs will be provided to Takeda at the completion of all the study activities. COR (CRA) should send a follow-up letter to the PI/ site staff using the template provided. The follow-up letter will outline any outstanding issues and corresponding actions. The letter can be written in the site's local language and an e-mail or a signed copy should be uploaded into Trial Master Files. The follow-up letter will be sent to the sites no later than 10 working days, as soon as the report of the previous visit is finalized. If significant issues are identified during the visit, the follow up letter should be sent to site within maximum 5 working days. Preferable, the follow-up letter must not have cumulative information in order to avoid misunderstanding of the PI / site staff. The outstanding data, action to be taken and resolutions provided must be highlighted and must be issued to the site staff in a timely manner	
		Results	Upon review of the eCRF data, the COR (CRA) document the reviewed visit and eCRF pages in monitoring visit reports.
		Tracking	All on-site visits will be tracked on the excel sheet with visit date to show the monitoring compliance.
		Reporting	Any MVR and communication process deviated from the monitoring plan will be tracked. The compliance rate should achieve 90% of the study. Any major discrepancies occurred will be reported to Takeda for CAPA discussion within 5 working days.
5. Issue Management: The requirements for management of clinical study protocol deviations should follow SOP-011 Quality Issue Management.			
	For all unresolved actions during site visits, significant findings and protocol deviations will be issued and documented in "Issue Tracking Log" Protocol Deviations (PDs) will be identified by CORs (CRAs) during routine monitoring visits during data review. PDs will be tracked in Issue Tracking log using the following Categories: Protocol Deviation: AE/SAE		

	Protocol Deviation: In/Excl Criteria Protocol Deviation: Others Follow-up Protocol Deviation Apply the following rules when entering Protocol Deviation in Issue Tracking Log: - Break down information for more than one subject by duplicating the entries per subject (if necessary for each subject) - Raise one Issue per Protocol Deviation - Don't use line breaks - Don't use special characters e.g., *, #
6. Adverse Event (AE), Serious Adverse Event (SAE) and Pregnancy Reporting	
	Provide details for how COR will review and follow-up regarding SAE and Pregnancy Reporting — As described in the project-specific protocol, events or complaints that are not part of the study objectives or endpoints will not be abstracted or collected from healthcare records or other applicable source records.
7. Interactive Response Technology IRT) – Provide additional details regarding the following items:	
	System — NAP
	Point of Contact for System Issues — NAP
8. Clinical Trial Material (CTM) - Procedures regarding CTM must be in accordance with the Pharmacy Manual.	
	NAP
9. Shipment, Ordering, and Inventory of Clinical Supplies at the Site	
	NAP
10. Investigator Site Files (ISF) – Provide details related to the following items:	
	Investigator Site File Content — The ISF structure will follow VISWIN TMF Index finalized on 20251123.

	Set Up	The ISF with regulatory documents will be provided before or on Site Initiation Visit to site staff by COR (CRA). The wet-ink documents will be filed in ISF or sent to Takeda according to Master TMF plan of this study.
	Maintenance	The ISF should be reviewed regularly according to section 4 of this Monitoring Plan to ensure it is completeness and current. A final review and reconciliation should be performed during the Termination Visit. All site-specific regulatory documents will be forwarded and filed in the trial master file defined in Master TMF Plan.
	Archival	All the study documents will be securely stored and archived after 10 years of study completion. All the wet-ink documents with subject personal information will be filed at study site and/or qualified archiving vendor only and other documents will be filed in both ISF and TMF.

GENERAL COMMENTS

This visit plan has been updated from Version 1.0, which previously addressed only the responsibilities and activities related to the Qualification Visit. The study information has been updated to reflect the current study status and is aligned with the finalized protocol, Version 1.0, dated 09 October 2025.

CLINICAL OPERATIONS REPRESENTATIVE APPROVAL			
PRINTED NAME	**TITLE**	**SIGNATURE**	**DATE**
MINNA CHEN	**SR. RWE SPECIALIST**	Signed by: Minna Chen Signer Name: Minna Chen Signing Reason: I approve this document Signing Time: 20-May-2026 | 12:14:00 IST B3F875263D9E4D7E8BE92082E0995901	20-May-2026 | 12:14:06 IST

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Notary Events	Signature	Timestamp

Envelope Summary Events	Status	Timestamps
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Payment Events	Status	Timestamps