INTERNATIONAL ACADEMIC PUBLICATION DOSSIER
THE VIEN GUT MODEL
Integrated Outpatient Care for Complex Chronic Multimorbidity

Part A – FOUNDATIONAL DOCUMENTS
DOCUMENT A.1
THE EBM REFERENCE FRAMEWORK: WHAT – HOW – DATA-to-operate

From the gap to an operationalizable structure

The Vien Gut Model — International Academic Publication Dossier

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Clinical implementation of HOW — risk stratification, window of opportunity, longitudinal follow-up, risk control, multidrug management, and activation of transfer safety valves.

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POSITION OF THIS DOCUMENT WITHIN THE ACADEMIC DOSSIER OF THE VIEN GUT MODEL

Document A.1 is not a document presenting a specific clinical workflow, nor is it a document applying the model to a single disease axis. A.1 is the foundational document of Part A, whose task is to establish the EBM reference framework used throughout the academic dossier of the Vien Gut Model: WHAT – HOW – DATA-to-operate.

If A.0 is the document that declares the overall architecture of the dossier, then A.1 answers the next question: what academic reference framework is this dossier using to look at the gap in modern medicine when caring for patients with complex chronic multimorbidity in the outpatient setting. A.1 therefore serves as the hinge between the architectural declaration in A.0 and the foundational conceptual set in A.2.

To read A.1 in its proper place, this document should be situated within the four-layer architecture of the dossier:

Layer 1 — Core architecture (Part A and Part B) A.1 belongs to Layer 1. It does not describe any single disease, but establishes the shared reference framework for all of Part A, Part B, Part C, and Part D.

Layer 2 — Application of the architecture to specific disease axes (Part C) The C documents can only be read correctly when the reader has first grasped A.1, because every C document operates on the same WHAT – HOW – DATA-to-operate framework.

Layer 3 — Appendices (protocols and procedures) The appendices are the detailed implementation layer of HOW. They cannot be understood separately from A.1, because without the reasoning framework in A.1, the reader may mistake protocols for a collection of disconnected clinical tricks.

Layer 4 — Academic dialogue, evidence benchmarking, and the roadmap to multicenter validation (Part D) Part D can only be formed academically if A.1 has already established the central question: what is modern medicine missing between evidence and practice, and what layer is the Vien Gut Model proposing in order to fill that gap.

GUIDE FOR THE READER OF A.1

- To understand the overall architectural declaration of the entire dossier, read A.0.
- To understand the precise definitions of the three layers WHAT – HOW – DATA-to-operate, read A.2.
- To understand the international evidence on the global HOW gap, read A.3.
- To understand the operational terminology system, read A.4–A.5.
- To understand how this framework is deployed into an outpatient model, read B.1–B.5.
- To understand how this framework is applied to each disease axis, read C.1–C.n.
- To understand how this framework will enter academic dialogue and multicenter validation, read Part D.

ABSTRACT

Document A.1 presents the EBM reference framework used by the academic dossier of the Vien Gut Model to analyze and organize outpatient care for patients with complex chronic multimorbidity. The central argument of the document is that the modern EBM chain has built the WHAT layer very strongly

— that is, treatment targets, evidence, guidelines, and single-disease recommendations — but has not by itself generated a sufficient HOW layer, that is, the clinical operating architecture needed to apply multiple guidelines simultaneously to one patient over time, nor has it provided the DATA-to-operate layer, that is, the longitudinal dataset required to activate the right clinical decisions at the right time in complex outpatient multimorbidity.

A.1 does not reject EBM. On the contrary, A.1 regards EBM as the irreplaceable foundation of modern medicine, but argues that when one moves from selected research populations to real-world patients with multiple severe diseases at once, the single-disease EBM chain encounters a structural break at the point of clinical application. From that point, the document proposes the three-layer framework WHAT – HOW – DATA-to-operate as a more complete reference system for translating guideline knowledge into integrated, individualized outpatient practice with longitudinal follow-up and the possibility of validation.

This framework is the direct theoretical foundation of all of Part B, Part C, and Part D. It is also the basis for explaining why high-level clinical targets — such as crystal-free status, dialysis delay, reduction of heart failure decompensation, and cirrhosis recompensation — despite already having an international evidence base, remain very difficult to realize sustainably in practice if there is no sufficiently strong operating model.

CONTEXT

Vien Gut began in 2007 when Vietnam was still a low-income country, with limited healthcare resources and a shortage of highly specialized physicians, while the model in its early phase relied mainly on a team of general internal medicine doctors. The patient population that Vien Gut received from the very beginning was not the group with mild gout, but primarily patients presenting late with severe gout complications, alongside chronic kidney disease, heart failure, cirrhosis, diabetes, secondary adrenal insufficiency, and many overlapping pathological spirals.

It was precisely in this patient group that a clinical paradox appeared very early: physicians could know more and more about international guidelines, yet treatment outcomes in the most difficult cases did not improve automatically simply by adding together multiple single-disease guidelines. The main problem was no longer a lack of treatment principles, but rather the absence of an operating architecture capable of simultaneously organizing multiple treatment targets, multiple medications, multiple risks of decompensation, and multiple rhythms of follow-up in one patient over time.

The year 2014 was an especially important milestone. From that point onward, through international collaboration, Vien Gut more systematically received the WHAT layer of treatment guidelines for gout and comorbid diseases. Yet the clearer the WHAT became, the more deeply the HOW gap in practice was exposed. In other words, the closer Vien Gut came to the international standard of evidence, the more clearly it saw that an additional layer was missing between guidelines and the reality of complex multimorbidity. A.1 was written to describe that missing layer precisely in structured academic language.

OBJECTIVES AND SCOPE OF THE DOCUMENT

Document A.1 has five objectives.

- First, to describe the modern EBM chain as the irreplaceable foundation of modern clinical medicine.
- Second, to identify the structural break in the EBM chain when moving from single-disease evidence to real-world application in patients with complex chronic multimorbidity in the outpatient setting.

• Third, to establish the three layers of the reference framework used by the Vien Gut Model: WHAT, HOW, and DATA-to-operate.

• Fourth, to explain the relationship among these three layers and why they neither replace nor compensate for one another.

• Fifth, to set this framework as the direct theoretical foundation for all of Part B, Part C, and Part D.

Document A.1 does not go deeply into detailed definitions of each individual operational term; that content belongs to A.2, A.4, and A.5. Nor does this document describe clinical workflows in detail; that content belongs to B.1–B.5. A.1 is a framework document: its task is to establish the academic reference framework, not to write out specific protocols.

1. THE PRACTICE-BASED ORIGIN OF THE WHAT – HOW – DATA-TO-OPERATE QUESTION

This document arises from a question that Vien Gut was forced to answer for itself after many years of clinical operation: why can physicians be better trained, guidelines more up to date, and therapies more diverse, yet when treating patients with complex chronic multimorbidity in the outpatient setting, outcomes still do not automatically improve in parallel?

The answer does not lie in poor-quality guidelines. On the contrary, guidelines have become increasingly better. The issue is that a guideline is only one part of the treatment architecture. It answers very strongly the question of “what needs to be done,” but does not fully answer the question of “how should it be organized in one patient who has multiple severe diseases, multiple medications, multiple risks, and multiple points of rupture over time.”

From that observation, Vien Gut gradually systematized an insight: between evidence and practice there are at least three layers that must be distinguished. One is the WHAT layer — treatment targets, guidelines, target thresholds, and preferred drugs. The second is the HOW layer — the clinical operating architecture that makes it possible to bring WHAT into real treatment. The third is the DATA-to-operate layer — the data set sufficient to detect trends, identify breakpoints, activate decisions, and sustain longitudinal follow-up.

A.1 is the first step in turning this insight into a transparent academic framework that can be examined, debated, and used as the foundation of the entire dossier.

2. THE MODERN EBM CHAIN — A GREAT ACHIEVEMENT, YET NOT A SUFFICIENT ARCHITECTURE FOR COMPLEX MULTIMORBIDITY

Evidence-based medicine has been built as a very strong logical chain. From basic scientific research, medicine gradually proceeds to diagnosis, the establishment of treatment targets, the development of drugs or interventions, clinical trials, evidence grading, and guideline construction. This entire chain is the greatest foundation of modern medicine, and no knowledge layer of the Vien Gut Model stands outside it.

STEP IN THE EBM CHAIN	METHODS AND CONTENT	OUTPUT	HOW + DATA
1. Basic research	In vitro/in vivo experiments, animal models, gene expression, proteomics — identifying pathophysiology and molecular targets	Hypotheses for diagnosis and treatment	No clinical HOW/DATA required

STEP IN THE EBM CHAIN	METHODS AND CONTENT	OUTPUT	HOW + DATA
2. Diagnostic development	Diagnostic criteria (ACR criteria), imaging techniques, biomarkers — evaluation of sensitivity and specificity	Tools for accurate disease recognition	Standardized diagnostic HOW — systematic diagnostic DATA
3. Treatment targets	Based on disease mechanisms and epidemiology — short-term and long-term goals; individualized under patient-centered care	WHAT becomes clearly formed: treatment targets are scientifically defined	HOW to achieve targets in single disease — DATA to evaluate single-axis results
4. Drug/intervention development	From screening to molecular design (for example, biologics such as anti-TNF), preclinical studies	Treatment tools with preclinical evidence	HOW to use therapy safely in single disease — preclinical DATA
5. Clinical trials	Phase I → Phase II → Phase III double-blind RCT → Phase IV; compliance with GCP	Evidence of efficacy and safety. NOTE: RCTs often exclude patients with severe multimorbidity	HOW under tightly controlled RCT conditions — homogeneous DATA. But the real-world population is excluded
6. Evidence hierarchy (OCEBM)	From low to high: expert opinion → cross-sectional → case-control, cohort → RCT → systematic review — assessed by GRADE	Evidence ranked according to OCEBM	Cross-sectional studies are useful for detecting gaps — population DATA but not longitudinal individual DATA
7. Guideline construction	Synthesized by EULAR, ACR, KDIGO, ESC, EASL, NICE, AHA, etc., through Delphi/consensus methods [2–8] — recommendations based on GRADE	WHAT completed at the highest level: standard international guidelines	Single-disease HOW is clear — but multimorbidity HOW and DATA-to-operate are NOT described
8. CLINICAL APPLICATION ← THE BREAKPOINT	A fragmented model — each specialty applies its own guideline without structured coordination	Outcomes fall short of expectations — the gap between efficacy and effectiveness	Integrated multi-axis HOW DOES NOT EXIST. DATA-to-operate is NOT structured. This is the gap that the Vien Gut Model fills

Seen from within the EBM chain, this is an extraordinary achievement. But when one moves to real-world application for patients with complex chronic multimorbidity, the chain reveals a limitation: it is very strong at producing correct evidence, but does not by itself produce a sufficient operating architecture for bringing that evidence into outpatient care for patients with multiple severe conditions at once.

In other words, modern EBM has done an excellent job of producing standard treatment knowledge, but this does not automatically mean that it has created enough organizational logic to apply that knowledge to the most difficult cases.

3. THE STRUCTURAL BREAK IN THE EBM CHAIN AT THE POINT OF CLINICAL APPLICATION

The breakpoint does not appear in basic research, does not appear in RCTs, and does not lie in the guidelines themselves. It appears at the point of clinical application, especially when the subject is no longer a single-disease patient but a patient with complex chronic multimorbidity.

In RCTs, patients are usually selected to reduce noise. Cases with multiple severe diseases at the same time, severe organ failure, complex multidrug regimens, or high risk are often excluded or only represented in very small proportions. Guidelines are therefore built mainly from populations that are "cleaner" than real clinical practice. But when guidelines enter real life, physicians must face the real patient — a patient from whom comorbidities cannot be "excluded" in order to fit the research population.

This is where what the Vien Gut Model calls a structural breakpoint appears: not because the guideline is wrong, not because the physician has not tried hard enough, but because an evidence system designed for single diseases must confront the reality of multiple diseases evolving over time.

At that point, three difficulties arise simultaneously:

- First, multiple individually correct guidelines may conflict when applied simultaneously to one patient.
- Second, the guidelines do not provide an overall coordinator.
- Third, the guidelines themselves do not come with a longitudinal data structure for making continuous decisions between visits.

Structural cause	Description
Single-disease guidelines	Each guideline is built from RCTs that exclude patients with severe multimorbidity. The evidence comes from "clean" populations — and that is a structural limitation, not an error.
No integration mechanism	No guideline describes how to coordinate care when a drug that is good for one axis is harmful to another.
No overall coordinator	The EBM chain ends at the step "the physician applies the guideline" — but does not define who carries overall responsibility.
No longitudinal data	Single-disease guidelines are based on cross-sectional slices. Chronic multimorbidity requires time-series data.

The result is that the gap between efficacy in research and effectiveness in real life becomes widest precisely in the most complex patients.

4. THE THREE-LAYER FRAMEWORK: WHAT – HOW – DATA-TO-OPERATE

From the limitation above, the Vien Gut Model proposes viewing outpatient care for complex chronic multimorbidity through three distinct but tightly connected layers: WHAT, HOW, and DATA-to-operate.

4.1. WHAT — the treatment knowledge layer

WHAT is the entire layer of evidence-based treatment knowledge: international guidelines, treatment targets, biochemical thresholds, preferred drugs, principles of initiation, principles of monitoring, and evaluation criteria. This is the layer that modern medicine has built very well and that the Vien Gut Model fully respects.

WHAT answers questions such as: what should the uric acid target be; when should urate-lowering therapy be initiated; how should CKD be assessed by GFR and albuminuria; which variables should be used to monitor heart failure; by which criteria should decompensated cirrhosis be defined and followed.

In short, WHAT is the answer to the question: what should be achieved, and by which principles should it be achieved.

4.2. HOW — the structured clinical operating layer

HOW is the layer of executional organization. It is not a new guideline, and it does not replace WHAT; rather, it is the operating architecture that enables WHAT to enter real treatment.

HOW answers questions such as: who holds the overall coordinating axis; how is a patient risk-stratified; when should follow-up be intensified and when can it be safely spaced out; when two guidelines conflict, what should be prioritized first; when a signal of decompensation appears, who responds, within what time frame, and according to which process; when transfer is needed, how is it carried out and how does reintegration occur afterward.

In the Vien Gut Model, HOW appears in forms such as the Clinical Conductor, phased treatment planning, T1–T4 stratification, multidrug management, transfer safety valves, the 0–30 day reintegration cycle, the role of the patient, and enabling conditions. All of Part B is precisely the HOW layer deployed as a concrete operating model.

In short, HOW is the answer to the question: how should care be organized so that WHAT can actually function in real patients.

4.3. DATA-to-operate — the decision-activating data layer

DATA-to-operate is not data stored merely for completeness, nor is it “big data” in the sense of sheer volume. It is the dataset sufficient for action. It is longitudinal data over time, organized so as to detect trends, identify breakpoints, define action thresholds, prompt responses at the right time, and keep clinical decisions from relying on a single isolated snapshot.

DATA-to-operate answers questions such as: is eGFR declining rapidly or remaining stable; is NT-proBNP rising as a trend or only fluctuating; are albumin, INR, and ascites opening or closing the window of opportunity; has uric acid reached target while the crystal burden is still decreasing or has it plateaued; is patient adherence still sufficient or at risk of rupture; when should the SLA be shortened, the monitoring tier escalated, or the safety valve activated.

In short, DATA-to-operate is the answer to the question: on which data should decisions be based in order to act at the right moment and maintain the right treatment rhythm.

5. THESE THREE LAYERS DO NOT REPLACE OR COMPENSATE FOR ONE ANOTHER

One of the points that must be made clearest in A.1 is that WHAT, HOW, and DATA-to-operate are not three different names for the same thing. Nor are they three options from which one can choose one and discard the other two. They are three different layers of the same architecture.

If WHAT is strong but HOW is weak, the physician knows what needs to be done but cannot organize it sustainably in a patient with complex multimorbidity.

If WHAT and HOW are present but DATA-to-operate is weak, the system may still operate, but it will make decisions on disconnected snapshots, react slowly, and miss breakpoints.

Only when WHAT, HOW, and DATA-to-operate are all sufficiently strong can treatment become a process that is predictable, traceable, risk-controllable, and verifiable.

Which layer is missing?	Consequence	Clinical illustration
HOW is missing	WHAT remains on paper and is not translated into integrated action	A patient with gout + CKD G4 + heart failure: three guidelines conflict and nobody coordinates them
DATA-to-operate is missing	HOW operates blindly, with decisions based on isolated snapshots	The Clinical Conductor does not see that eGFR is sliding downward and activates the safety valve too late
WHAT is missing	HOW + DATA operate without a standard	This does not occur in the Vien Gut Model — WHAT is always preserved intact from international guidelines

Therefore, the WHAT – HOW – DATA-to-operate framework does not seek to diminish the role of guidelines. On the contrary, it seeks to protect the value of guidelines by placing them within an architecture that is sufficient to move from knowledge to operation.

6. WHY THIS FRAMEWORK MATTERS FOR THE FOUR VALIDATION TARGETS OF THE MODEL

Crystal-free status, dialysis delay, reduction of heart failure decompensation, and cirrhosis recompensation are all targets for which international evidence has already shown feasibility to differing degrees. But what those bodies of evidence have in common is that they were usually generated in settings with patient selection, clear protocols, dense rhythms of assessment, and tightly controlled event-management teams.

Validation target	WHAT + HOW + DATA
C.1 Crystal-free	WHAT: Treat-to-target urate lowering according to ACR/EULAR [3,4]. HOW: The Clinical Conductor phases treatment and manages multidrug therapy with renal and hepatic safety. DATA: serial sUA, OMERACT ultrasound, DECT.
C.2 Kidney preservation	WHAT: KDIGO 2024 [5] for CKD management. HOW: Resolving conflicts between urate-lowering therapy and kidney function, with dose adjustment according to eGFR. DATA: eGFR series, K^+ , creatinine, renal ultrasound.
C.3 Reduction of heart failure decompensation	WHAT: ESC 2021 [6] for heart failure. HOW: Balancing diuretics, urate lowering, and kidney protection, with intensified monitoring rhythm

Validation target	WHAT + HOW + DATA
	when BNP rises. DATA: serial BNP/NT-proBNP, EF, troponin.
C.4 Cirrhosis recompensation	WHAT: EASL 2018 [7] for decompensated cirrhosis. HOW: Multidrug management to avoid hepatotoxicity, albumin adjustment, and coagulation surveillance. DATA: Child–Pugh, FibroScan, serial albumin, PT-INR.

In other words, the international literature itself has indirectly shown that in order to reach high-level treatment targets, knowing WHAT is not enough. A sufficiently strong architecture is needed to organize treatment rhythm, follow-up rhythm, phase-transition management, multidrug management, intervention when decompensation signals appear, and continuity of care over the long term.

That is exactly why A.1 must stand at the foundation of the entire dossier. If the WHAT – HOW – DATA-to-operate framework is not established, then the four validation targets in A.0 can easily be read as four disconnected goals. But what the Vien Gut Model seeks to demonstrate is not merely each target in isolation; it is the value of an integrated architecture capable of pursuing those targets simultaneously in complex outpatient multimorbidity.

7. IMPLICATIONS FOR THE VIEN GUT MODEL

From this framework, the role of the Vien Gut Model can be defined more clearly.

- The Vien Gut Model does not seek to replace guidelines.
- The Vien Gut Model does not seek to create a “reference system outside EBM.”
- The Vien Gut Model does not deny the value of international evidence.

What this model does is add the two missing layers between guidelines and practice: HOW and DATA-to-operate. In the context of outpatient patients with complex chronic multimorbidity, these are not optional additions; they are the conditions under which WHAT can become real outcomes.

In this sense, A.1 is the document that lays the theoretical foundation for the entire operational and application parts of the dossier. Without A.1, Part B can easily be misunderstood as a collection of clinical management experience. Without A.1, Part C can easily be misunderstood as a series of disease-based reports. Without A.1, Part D would also struggle to enter rigorous international academic dialogue. A.1 is precisely the bridge from classical EBM to a more suitable integrated outpatient architecture for patients with complex chronic multimorbidity.

8. LIMITS OF THE DOCUMENT’S SCOPE

Document A.1 includes: a description of the modern EBM chain; identification of the structural breakpoint of EBM at the point of clinical application; establishment of the three layers WHAT – HOW – DATA-to-operate; an explanation of the relationship among these layers; and the placement of this framework as the theoretical foundation of the entire academic dossier of the Vien Gut Model.

Document A.1 does not include: detailed definitions of each operational term; the standardized glossary; clinical protocols; detailed descriptions of each component of the Clinical Conductor, risk stratification, window of opportunity, the role of the patient, or enabling conditions; nor does it present each disease axis or the detailed roadmap to multicenter validation. Those contents belong to A.2–A.5, B.1–B.5, C.1–C.n, and Part D.

9. THE POSITION OF A.1 WITHIN THE VIEN GUT DOCUMENT SYSTEM

A.1 is the direct theoretical foundation document of the entire dossier. After A.0, this is the first document that the reader must grasp in order to understand why the academic dossier of the Vien Gut Model has to be organized in multiple layers, why guidelines are not by themselves sufficient to answer the outpatient problem of complex multimorbidity, and why this model must add the HOW and DATA-to-operate layers.

From A.1, the reader can proceed to A.2 to grasp the definitions of the three layers, to A.3 to see the international evidence on the HOW gap, to Part B to read the operating model, to Part C to read the application by disease axis, and to Part D to enter academic dialogue and validation. If A.0 is the architectural declaration, then A.1 is the reference map of the entire dossier.

CONCLUSION

Modern medicine has built a very strong EBM chain for generating evidence, guidelines, and standard treatment targets. But when it enters outpatient treatment for patients with complex chronic multimorbidity, that chain reveals a structural breakpoint at the stage of clinical application. From nearly two decades of practice in patients with severely complicated gout alongside complex chronic multimorbidity, Vien Gut has reached a foundational conclusion: in order to translate the WHAT of guidelines into real outcomes, HOW and DATA-to-operate must be added as two indispensable architectural layers.

The WHAT – HOW – DATA-to-operate framework is therefore not a slogan. It is the academic reference system used to explain, organize, and validate the entire Vien Gut Model. This is the central theoretical contribution of A.1, and it is also the foundation that allows all subsequent documents in the dossier to stand as a unified academic architecture.

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Foundational and operational documents within the academic dossier of the Vien Gut Model: A.0, A.2–A.5, B.1–B.5, C.1–C.n.