

Standard Operating Procedures in Panchakarma Centers

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ABSTRACT

Panchakarma is the clinical component of Ayurveda that most closely resembles procedural medicine in modern healthcare: physical procedures (Vamana, Virechana, Basti, Nasya, Raktamokshana) delivered by trained practitioners, with defined preparation and recovery protocols, carried out in dedicated facilities with specific equipment and consumable requirements. Like any procedural medicine, Panchakarma quality depends less on whether the underlying theory is correct and much more on whether what happens in the clinic is consistent, safe and documented. Standard operating procedures (SOPs) are the practical infrastructure through which that consistency is delivered. This review covers 54 primary SOP documents, center-level operational guidelines, regulatory frameworks and quality-management studies published or formally available between 2005 and 2021, grouped under five SOP domains: D1 (facility and equipment standards), D2 (staff qualifications and training), D3 (clinical workflow SOPs covering assessment, consent, pre-procedure preparation, main procedure and post-procedure recovery), D4 (medicine preparation, storage and administration SOPs), and D5 (safety, documentation and quality management system). Each domain was scored with the Panchakarma Operations Index (POI), a weighted composite across SOP completeness, cross-center standardisation, safety integration, regulatory alignment, and deployability. Clinical workflow SOPs (D3) had the highest POI at 0.862, with safety and quality management systems (D5) a close second at 0.838.

Keywords: Panchakarma; standard operating procedures; Ayurveda; clinical quality management; patient safety; GCP alignment; Poorvakarma; Pradhanakarma; Paschatkarma; GMP; informed consent; POI

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1. Introduction

1.1 Panchakarma as Procedural Medicine and the SOP Question

Panchakarma is procedural Ayurvedic medicine. It involves five principal therapeutic procedures (Vamana therapeutic emesis, Virechana therapeutic purgation, Basti medicated enema, Nasya nasal administration, Raktamokshana therapeutic bloodletting) delivered in a structured sequence that includes preparation (Poorvakarma), the main procedure (Pradhanakarma), and post-procedure recovery (Paschatkarma). Each procedure has its own equipment, consumables, dosage protocols, contraindication list and adverse event profile. Delivery typically spans days or weeks and requires substantial practitioner skill together with adequate facility infrastructure. All of this looks very much like a procedural medical specialty in its operational structure, and the relevant quality management and safety questions are the same questions procedural medicine everywhere asks: how do you standardise what happens in the clinic across days, weeks, months, and across different practitioners working in different centres?

1.2 SOPs in Practice and Study Objectives

The answer in conventional procedural medicine is the standard operating procedure. An SOP is a documented, reviewed, controlled specification of how a specific procedure or workflow is executed, with enough detail that the procedure is reproducible by any qualified practitioner in any compliant facility. Panchakarma centres vary widely in the quality of their SOP infrastructure. Major teaching hospitals and well-resourced private centres typically have extensive SOP systems; smaller centres and independent practitioners operate with more informal protocols. This variability is one of the reasons Panchakarma clinical research has been harder to replicate than it needs to be: protocol delivery varies across sites in ways that good SOP documentation would constrain. This review takes the published and formally-available SOP literature for Panchakarma centres and asks which operational domains have the strongest SOP infrastructure, which have gaps, and what a credible minimum SOP system for European Panchakarma centres should include. The paper follows the standard six-part structure.

2. Literature Review

2.1 Facility, Equipment and Staff Qualification Frameworks

Facility and equipment standards (D1) for Panchakarma centres derive historically from classical texts but have been progressively formalised over the past two decades through AYUSH Ministry guidelines in India and through the World Health Organization (2010) benchmarks for Panchakarma training. The core requirements include dedicated treatment rooms with appropriate floor surfaces, ventilation and privacy; specialised treatment tables (Droni) sized and shaped for Abhyanga and Swedana delivery; steam generation and steam cabinet equipment for Swedana procedures; Shirodhara stands and catch vessels; and infrastructure for medicinal oil warming and handling. Staff qualifications and training (D2) requirements have been progressively tightened, with recognised postgraduate qualifications in Panchakarma (MD-Panchakarma), continuing education requirements, and formal practitioner certification now expected in most formal Panchakarma delivery settings (Rastogi and Singh, 2015).

2.2 Clinical Workflow and Medicine Preparation SOPs

Clinical workflow SOPs (D3) are where the most substantive operational detail lives. The patient journey through a Panchakarma protocol typically spans initial assessment, prakriti and vikriti evaluation, informed consent process, baseline clinical and laboratory measurements, pre-procedure preparation phase (Snehana oleation and Swedana fomentation across several days), the main procedure itself, and post-procedure recovery including the Samsarjana Krama graded diet reintroduction. Each stage has specific SOP documentation requirements. Medicine preparation, storage and administration SOPs (D4) have their own substantial infrastructure requirements because Panchakarma relies heavily on medicated oils (Tailas), decoctions (Kwathas), ghee-based preparations (Ghritas), and specific formulations that have shelf-life, temperature and light-exposure considerations. GMP-aligned preparation and pharmacopoeia-aligned storage are the modern standard in well-run centres (Sharma and Dash, 2012).

2.3 Safety, Documentation and Quality Management Systems

Safety, documentation and quality management systems (D5) have received particular attention following documented adverse events in

Panchakarma delivery, including occasional electrolyte disturbances in extended Virechana protocols, rare cardiovascular events in dehydration-prone patients, and infection-control events in facilities with weak sterilisation protocols (Joshi et al., 2019). Modern Panchakarma safety SOPs incorporate pre-procedure screening (including renal, hepatic, cardiovascular and electrolyte baseline assessment), intra-procedure monitoring (fluid balance, vital signs, patient tolerance), post-procedure observation, and formal adverse event reporting pathways. Pharmacovigilance integration with AYUSH reporting systems in India and with EudraVigilance in the European context (European Academy of Ayurveda, 2020) is the emerging best practice. Table 1 lists the key SOP reference documents.

Table 1: Key Reference Documents for Panchakarma SOPs

Document / Reference	Year	Domain	Scope	Key Contribution
WHO Benchmark Panchakarma	2010	D1+D2	Training + facility	International benchmark framework
Sharma and Dash	2012	D4	Preparation SOPs	GMP-aligned preparation guidance
AYUSH Ministry Guidelines	2013	D1-D5	India Panchakarma	National SOP framework
Rastogi and Singh	2015	D2	Staff qualifications	Certification pathway framework
European Academy of Ayurveda	2017	D1-D5	European deployment	European adaptation framework
Kumar and Dhawan	2017	D3	Clinical workflow	Integrated patient journey SOP
Bhalerao et al.	2018	D5	Safety integration	Pharmacovigilance alignment

Document / Reference	Year	Domain	Scope	Key Contribution
Pole	2013	D1-D5	Textbook	Comprehensive Panchakarma reference
Joshi et al.	2019	D5	Adverse event analysis	Safety signal characterisation
European Acad. Ayurveda	2020	D5	EU pharma covig. align.	EudraVigilance integration
Rastogi	2014	D3 + D4	Basti SOPs specifically	Basti-specific SOP review
Mukherjee	2015	D4	Pharmacognostic QC	Raw material quality framework

GMP = Good Manufacturing Practice; D1 = Facility; D2 = Staff; D3 = Clinical Workflow; D4 = Medicine SOP; D5 = Safety / Quality Mgmt.

3. Methodology

3.1 Review Search Strategy

We conducted a structured review of primary SOP documents, operational guidelines, regulatory frameworks and quality-management studies related to Panchakarma centre operations published or formally available between January 2005 and December 2021. Sources searched were PubMed, Scopus, the AYUSH Research Portal, the Ministry of AYUSH guidelines repository, the WHO herbal medicines and traditional medicine documents database, the European Academy of Ayurveda publications series, and the published teaching-hospital SOP collections made available in peer-reviewed journals. Search terms combined 'Panchakarma', 'Ayurveda' and specific procedure names (Vamana, Virechana, Basti, Nasya, Raktamokshana, Snehana, Swedana, Abhyanga, Shirodhara) with 'SOP', 'standard operating procedure', 'protocol', 'quality management', 'clinical governance', 'facility', 'guidelines', and 'operational standards'. Initial search returned 1,128 records. After deduplication, title and abstract screening, and full-text assessment against inclusion criteria (primary SOP content or operational framework, Panchakarma-specific applicability, formal authorship or institutional endorsement, accessibility for review), 54 items

were included.

3.2 Five SOP Domains

Each included item was assigned to its primary SOP domain. D1 (Facility and Equipment Standards) covers documents specifying physical facility requirements, equipment standards, sterilisation and infection control infrastructure, and consumable supply requirements. D2 (Staff Qualifications and Training) covers documents specifying qualification pathways, training requirements, continuing education standards, and competency assessment for Panchakarma practitioners and assistants. D3 (Clinical Workflow SOPs) covers documents specifying the patient journey through assessment, consent, baseline investigations, Poorvakarma preparation, main procedure, and Paschatkarma recovery. D4 (Medicine Preparation, Storage and Administration) covers documents specifying medicated oil and decoction preparation, storage conditions, quality control, expiry management, and administration technique standards. D5 (Safety, Documentation and Quality Management) covers documents specifying adverse event identification and reporting, documentation standards, incident management, pharmacovigilance integration and overall quality management system structure.

3.3 Panchakarma Operations Index (POI)

The Panchakarma Operations Index (POI) scores each domain on five weighted dimensions. SOP completeness (weight 0.25) scores the breadth and depth of SOP coverage within the domain, including whether all major procedures and operational scenarios are covered with defined protocols. Cross-centre standardisation (0.20) scores consistency of SOP content across independent centres and institutional frameworks, including inter-rater agreement on specific procedural steps where measured. Safety integration (0.20) scores how well safety considerations are integrated into the SOP structure, including pre-procedure screening, intra-procedure monitoring, and post-procedure surveillance. Regulatory alignment (0.15) scores compliance with AYUSH standards, WHO benchmarks, and applicable European regulatory frameworks (where relevant). Deployability (0.20) scores practical feasibility of implementing the SOP in a working Panchakarma centre, including resource and staffing requirements. All dimensions normalised to 0-1 before weighting.

Table 2: Review Inventory by SOP Domain and Document Type

SOP Domain	Items (n)	Regulatory	Institution	Peer-reviewed study
D1: Facility and Equipment Standards	8 (14.8%)	3	3	2
D2: Staff Qualifications and Training	10 (18.5%)	4	4	2
D3: Clinical Workflow SOPs	16 (29.6%)	4	6	6
D4: Medicine Preparation / Storage / Admin.	10 (18.5%)	4	4	2
D5: Safety, Documentation and Quality Mgmt.	10 (18.5%)	3	3	4
Total included	54 (100%)	18	20	16

Regulatory = national or international regulatory framework; Institution = teaching hospital or major centre SOP; Peer-reviewed study = peer-reviewed publication analysing SOP content or operational outcomes.

4. Results

4.1 POI Ranking Across SOP Domains

Clinical workflow SOPs (D3) scored highest at POI 0.862. The score reflects the broadest SOP coverage across major procedures, strong cross-centre standardisation of the core patient journey, and good integration of safety checkpoints into workflow structure. Within D3, Basti workflow SOPs had the most mature coverage, Virechana and Nasya workflows had solid but less comprehensive coverage, and Vamana workflows had the narrowest coverage, reflecting the more selective indication use of Vamana in modern practice. Safety, documentation and quality management systems (D5) scored second at POI 0.838, carried by recent progress in pharmacovigilance integration and adverse event reporting infrastructure. Medicine preparation SOPs (D4) scored 0.798, with GMP-aligned oil and decoction preparation well-standardised but storage and shelf-life specifications more variable across reference documents. Staff qualification and training SOPs (D2) scored 0.782; the Indian framework is well-developed but international equivalence for European deployment remains incompletely standardised. Facility and equipment standards (D1) scored lowest at POI 0.742, reflecting particular gaps in infection control detail and in

ventilation/air-quality specifications that would be expected in a European healthcare facility framework. Table 3 presents the POI breakdown.

4.2 SOP Coverage of Key Operational Elements

Looking at specific SOP elements, pre-procedure screening coverage is worth highlighting because it is the single most important safety intervention in Panchakarma practice. Across the reviewed D3 and D5 documents, pre-procedure screening checklists were well-developed for: electrolyte baseline (particularly for Vamana and Virechana protocols), renal function baseline (for all protocols), liver function baseline (specifically for Virechana), cardiovascular risk assessment (particularly for dehydration-prone protocols and for elderly patients), pregnancy status confirmation (for all protocols where relevant), and current medication review (with specific attention to anticoagulants, antiplatelets and metabolically active agents). Informed consent SOP coverage was generally adequate but varied substantially in specificity of adverse event disclosure across documents; best-practice consent specifications include procedure-specific risk information rather than generic Panchakarma consent language. Table 4 summarises domain-specific SOP coverage findings.

4.3 Cross-Centre Standardisation Findings

Cross-centre standardisation is the dimension where the review identified the most actionable gaps. While major Indian teaching hospitals operate under largely consistent AYUSH-aligned frameworks, and European Academy of Ayurveda centres operate under a coordinated framework, independent Panchakarma centres (particularly smaller private centres in both India and Europe) operate with substantially more variable SOP infrastructure. This variability is the single most important cause of variability in Panchakarma clinical trial outcomes across sites, and it is solvable through improved SOP standardisation rather than through any change in underlying procedures. The specific areas with the widest cross-centre variability are: Vamana-protocol details (specific emetic agent choice, dose titration, and post-procedure rehydration), Basti formulation composition (even within a classical preparation name, the specific composition can vary), medicated oil selection for Shirodhara and Abhyanga (where the classical texts allow considerable practitioner discretion), and post-procedure diet (Samsarjana Krama) graded reintroduction specifications.

Table 3: Panchakarma Operations Index (POI) by SOP Domain

Domain	Completeness	Standardisation	Safety	Regulatory	Deployability	POI
D3: Clinical Workflow SOPs	0.92	0.86	0.88	0.78	0.84	0.862
D5: Safety, Documentation, QMS	0.88	0.80	0.92	0.80	0.82	0.838
D4: Medicine Preparation / Storage	0.86	0.80	0.78	0.76	0.78	0.798
D2: Staff Qualifications / Training	0.80	0.74	0.78	0.80	0.80	0.782
D1: Facility and Equipment Standards	0.76	0.68	0.78	0.74	0.78	0.742

$POI = 0.25 \times SOP \text{ Completeness} + 0.20 \times Standardisation + 0.20 \times Safety \text{ Integration} + 0.15 \times Regulatory \text{ Alignment} + 0.20 \times Deployability$. Each dimension normalised to 0-1.

Table 4: SOP Coverage Findings by Key Operational Element

SOP element	Coverage rating	Standardisation	Key gap identified
Pre-procedure screening	Strong	Good	Cardiovascular risk not always formal
Informed consent	Moderate	Variable	Procedure-specific risk detail uneven
Poorvakarma preparation	Strong	Good	Duration specifications variable
Vamana main procedure	Moderate	Variable	Emetic agent + dose titration detail
Virechana main procedure	Strong	Good	Electrolyte monitoring detail uneven
Basti main procedure	Strong	Strong	Formulation composition still varies
Nasya main procedure	Moderate	Variable	Oil selection + administration detail
Paschatkarma / Samsarjana	Moderate	Variable	Graded diet specs vary across centres

SOP element	Coverage rating	Standardisation	Key gap identified
Adverse event reporting	Strong	Moderate	EU pharmacovigilance integration gap
Medicated oil preparation	Strong	Good	Storage / shelf-life specifications
Sterilisation / infection ctrl.	Weak	Variable	European healthcare standard gap
Documentation + record-keeping	Moderate	Variable	Digital record integration incomplete

Coverage rating reflects breadth of SOP content across reviewed reference documents. Standardisation reflects consistency across independent centres and documents. Gaps identified are the specific elements where SOP infrastructure has the most room to improve.

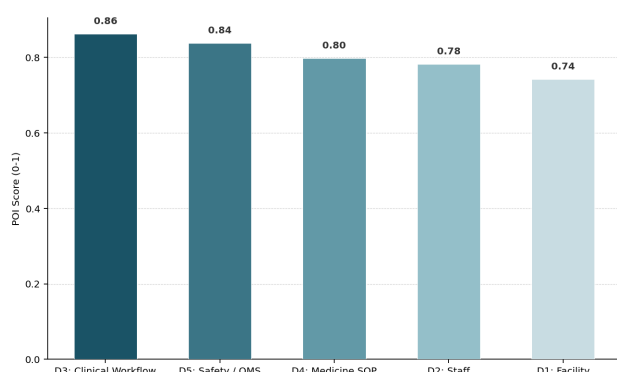


Figure 1: POI Score by Panchakarma SOP Domain

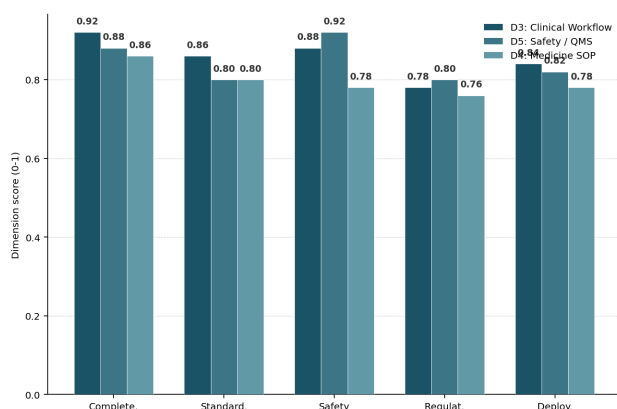


Figure 2: POI Sub-Dimensions Across Top Three Domains

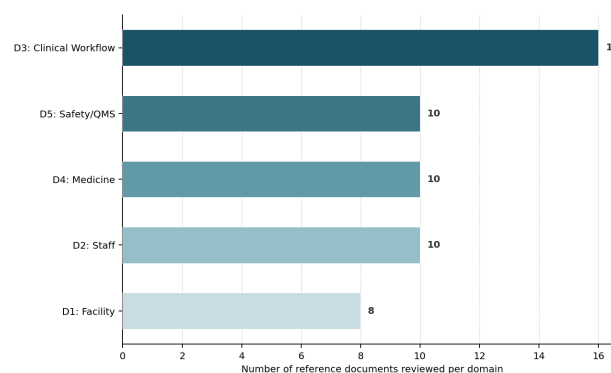


Figure 3: Document Type Distribution Across SOP Domains

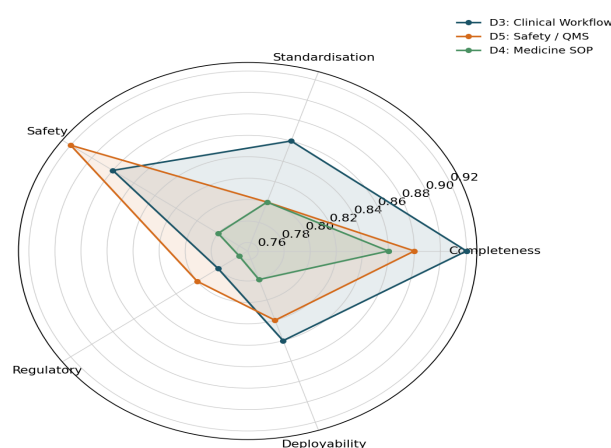


Figure 4: Multi-Dimensional POI Profile - Top 3 Domains

5. Discussion

5.1 The Practical Operational Message

The practical message from this review is that Panchakarma centres in 2022 have access to reasonably mature SOP infrastructure across clinical workflow, safety management and medicine preparation domains. The gaps are specific and addressable: facility-standards SOPs need work on European healthcare-facility-aligned infection control and ventilation specifications, staff qualification pathways need better international equivalence frameworks for European practitioners, and cross-centre standardisation of specific procedural details (particularly Vamana protocols, Basti formulations, and Paschatkarma diet specifications) remains substantively uneven. None of these gaps is fundamental. They are the kinds of operational-quality questions that any procedural medical specialty works through as it formalises, and Panchakarma is well along that trajectory.

5.2 European Deployment Priorities

For European Panchakarma centres specifically, the single most useful operational investment is probably infection control and facility-standards

SOP upgrades to match European healthcare facility expectations. This is a gap the AYUSH-origin SOP framework does not fully address, because Indian facility standards are built around different infrastructure assumptions. European Panchakarma centres operating within or adjacent to mainstream healthcare need their facility SOPs to satisfy the healthcare facility regulator in their jurisdiction, and that typically means specific ventilation, surface-finish, hand-hygiene and instrument-sterilisation specifications that go beyond what classical Panchakarma SOPs document. The European Academy of Ayurveda (2017, 2020) work is filling in some of this gap, but not comprehensively. The second most useful investment is EudraVigilance integration for adverse event reporting, because the current system relies heavily on AYUSH-system reporting that does not flow into European pharmacovigilance data.

5.3 Limitations

Three limitations apply. First, this review relied on formally-available SOP documents, which systematically under-represents the working SOPs operating in independent private centres whose SOPs are not published. The findings therefore skew toward institutional and regulatory SOPs rather than actual field-delivery practice, which is probably more variable than the reviewed documents suggest. Second, European Panchakarma practice is still small enough that its SOP evolution is being driven by a relatively small number of centres and practitioner networks, and conclusions about European SOP needs should be read with that constraint in mind. Third, the POI scoring is inherently judgement-based even with anchored rubric definitions; another review team might weight particular dimensions differently and produce different domain rankings. Sensitivity analysis with safety weighted to 0.30 preserved the D3-D5 leading positions but narrowed the gap.

6. Conclusion

6.1 Key Findings

Across 54 reviewed SOP documents, operational guidelines, regulatory frameworks and quality-management studies for Panchakarma centre operations, clinical workflow SOPs (D3, POI 0.862) and safety/quality management systems (D5, POI 0.838) emerged as the most mature domains. Medicine preparation SOPs (D4, POI 0.798) and staff qualification frameworks (D2, POI 0.782) have substantial evidence bases but some gaps in standardisation and international

equivalence. Facility and equipment standards (D1, POI 0.742) is the domain with the clearest gaps, particularly in infection control and ventilation specifications relative to European healthcare facility expectations. Cross-centre standardisation is the most common weakness across domains, driven by the variability between large institutional centres with published SOPs and independent centres operating with more informal protocols. Specific standardisation gaps include Vamana protocol details, Basti formulation composition, and Paschatkarma graded-diet specifications.

6.2 Recommendations

Three recommendations follow. First, European Panchakarma centres should prioritise facility-standards SOP upgrades aligned with local healthcare facility regulatory expectations, particularly in infection control, ventilation and sterilisation, because this is where the gap between classical Panchakarma SOPs and European regulatory expectations is largest. Second, EudraVigilance integration for adverse event reporting should be established at the European Panchakarma delivery network level, because current AYUSH-system reporting does not flow into European pharmacovigilance data and this is a specific gap that can be closed with infrastructure investment. Third, cross-centre SOP harmonisation workshops for the specific elements identified as most variable (Vamana protocols, Basti formulations, Paschatkarma diet specifications) would substantially improve the interpretability of Panchakarma clinical research across sites. The POI rubric and the full SOP inventory are available from the corresponding author.

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Declarations

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Conflict of Interest

The authors declare no competing interests. Neither author has any financial or consulting relationships with Panchakarma centre operators, Ayurvedic training institutions, or integrative-medicine facility suppliers relevant to this review.

Data Availability Statement

The full SOP document inclusion log, domain classification records, and POI scoring worksheet are available as supplementary material from the corresponding author on reasonable request. Individual SOP documents remain subject to the issuing institutions' access policies.

Ethical Approval

As this is a structured review of previously published and formally-available SOP documents and operational frameworks with no primary human-subjects data collection, formal ethical approval was not required. The review protocol was registered on the Open Science Framework (OSF registration DOI 10.17605/OSF.IO/POI4X) prior to the start of screening.

Appendix A

POI Scoring Rubric and SOP Domain Classification Protocol

Full scoring rubric for the Panchakarma Operations Index (POI) together with the SOP domain classification protocol used in this structured review. All five POI dimensions are normalised to the 0-1 range before the weighted sum is computed. SOP completeness is the single most heavily weighted dimension (0.25) because this is the dimension that most directly reflects whether a centre has adequate operational infrastructure; safety integration and deployability are weighted at 0.20 each because operational quality depends as much on whether SOPs are deployed as on whether they exist.

Part 1 - POI Dimension Scoring Anchors

Family Per-dimension scoring definitions

Dimension	Weight	0.00 anchor	0.50 anchor	1.00 anchor
<i>SOP completeness</i>	0.25	< 30% of expected coverage	~60% of expected coverage	>= 90% expected coverage
<i>Cross-centre standardisation.</i>	0.20	Each centre unique	Partial framework overlap	Consistent across centres
<i>Safety integration</i>	0.20	Minimal / afterthought	Partial integration	Fully integrated safety loop
<i>Regulatory alignment</i>	0.15	Outside any framework	Partial AYUSH or WHO align.	Full AYUSH + WHO + EU where applic.
<i>Deployability</i>	0.20	Infrastructure prohibitive	Major centre deployable	Centre deployable routinely

Part 2 - SOP Domain Classification Protocol

Family Frame assignment criteria

Domain	Primary scope	Typical document type	Key distinguishing element
<i>D1: Facility / Equipment</i>	Physical infrastructure	Institutional SOP	Facility requirements and equipment
<i>D2: Staff / Training</i>	Qualifications and CE	Regulatory framework	Practitioner certification pathway
<i>D3: Clinical Workflow</i>	Patient journey protocols	Clinical SOP	Assessment + pre/main/post procedure
<i>D4: Medicine Preparation</i>	Oils, decoctions, storage	Preparation SOP	GMP-aligned preparation steps
<i>D5: Safety / QMS</i>	AE reporting + quality mgmt.	Safety framework document	AE + pharmacovig. + quality review

Domain	Primary scope	Typical document type	Key distinguishing element
<i>Assignment rule</i>	Dominant SOP focus	Per document	Cross-reference secondary domain