PATIENT FOCUSED LABORATORY MEDICINE (PFLM) GROUP

5-YEAR STRATEGY (2026–2030)

Bridging Clinical Governance and Analytical Excellence to Improve Patient Outcomes

"It's never just about the laboratory, it's always about the patient"

Prepared by the PFLM Board
In Partnership with GIRFT Pathology, Birmingham Quality, Weqas and Bedfordshire Hospitals NHS Foundation Trust
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1. Executive Summary & Core Identity

The Patient Focused Laboratory Medicine (PFLM) Group was founded as a bottom-up, voluntary, expert coalition in direct response to the critical 2024 HbA1c analytical incident. That pre-analytical and analytical issue led to the misdiagnosis of thousands of patients across the UK and highlighted structural vulnerabilities within the nation's laboratory diagnostic infrastructure. Guided by our foundational strapline, "*It's never just about the laboratory, it's always about the patient*," this 5-year strategy document establishes an operational and clinical roadmap to transform the UK's quality infrastructure. By aligning pre-market validation with robust post-market vigilance, setting clinical utility-driven performance standards, and eliminating unwarranted clinical and analytical variation, the PFLM Group aims to put patient safety at the absolute centre of every diagnostic intervention.

2. Membership

GIRFT Pathology Co-Clinical Lead	Dr. Martin Myers
Clinical Representative	Dr. Danielle Freedman
Laboratory Representative	Dr. David Housley
Birmingham Quality	Mr. Finlay MacKenzie
Birmingham Quality	Dr. Rachel Marrington
Weqas	Mrs. Annette Thomas
Weqas	Mr. Gareth Davies

Table 1: Core membership of the PFLM Board

3. Acronyms

ABHI	Association of British HealthTech Industries
APS	Analytical Performance Specifications
BIVDA	British In Vitro Diagnostics Association
CERSI	Centre of Excellence for Regulatory Science and Innovation
EQA	External Quality Assessment
GIRFT	Getting It Right First Time
IBMS	Institute of Biomedical Sciences
IQC	Internal Quality Control
LabMed	Association for Laboratory Medicine
MSC	Managed Service Contract
NICE	National Institute for Health and Care Excellence
IVD	In Vitro Diagnostics
MHRA	Medicines and Healthcare products Regulatory Agency
PFLM	Patient Focused Laboratory Medicine
PMS	Post-Market Surveillance
POCT	Point of Care Testing
QMS	Quality Management System
RCPath	The Royal College of Pathologists
UKAS	United Kingdom Accreditation Service

4. Achievements and Progress to Date

Since its inception in late 2024, the PFLM Group has operated rapidly without central funding, driven entirely by clinical dedication. Key milestones achieved to date include:

- National Mobilisation Webinars: Organized two successful high-profile clinical webinars (November 2025 and May 2026), each attracting over 1,000 registered laboratory professionals, clinicians, and regulatory stakeholders to align the post-incident recovery strategy.
- Critical Peer-Reviewed Publications: Produced a comprehensive national meeting report in February 2026 titled 'Getting it right for the patient, are we good enough?'.[1] This milestone work was subsequently expanded and published as an open-access opinion paper in Clinical Chemistry and Laboratory Medicine (CCLM, June 2026), titled 'Clinical quality in UK laboratory medicine: current status and what the wider laboratory community can learn'.[2]
- Organisational Endorsements: Gained formal high-level endorsements for our clinical quality frameworks from Bedfordshire Hospitals NHS Foundation Trust, Birmingham Quality (member of the UK NEQAS consortium), Weqas, and NHS England's Getting It Right First Time (GIRFT) Pathology programme.
- Stakeholder and Digital Infrastructure: Established our official web presence (www.pflm.org.uk) and built an organic network of nearly 500 active professional followers across LinkedIn, published in LabMed News,[3] and online at westgard.com.[4]

5. Current Operational Projects

The PFLM Group is actively managing several high-impact diagnostic surveillance and regulatory projects:

1. The Yellow Card Survey and Manuscript: A comprehensive national audit mapping the utilisation patterns and barriers of the Medicines and Healthcare products Regulatory Agency's (MHRA) adverse incidence reporting mechanism (the Yellow Card System) has been successfully executed. The resulting manuscript is currently undergoing peer review with the Journal of Patient Centricity.
2. The National Quality Census (July 1, 2026): A single-time-point nationwide clinical biochemistry audit designed to capture a comprehensive baseline of automated analytical capacity and quality control processes across NHS Trusts. Crucially, this measures quality infrastructure nationally.
3. Webinar 3 is focused on Point-of-Care Testing (POCT): Scheduled for November 2026, this national event will focus entirely on quality architecture for decentralised and near-patient testing, bridging the gap between hospital labs and community healthcare pathways as well as direct-to-consumer-testing.
4. The Centre of Excellence for Regulatory Science and Innovation for In Vitro Diagnostics (CERSI IVD) Post-Market Surveillance (PMS) Initiative: Acting as a core stakeholder in the CERSI IVD project to scope future national directions for PMS using External Quality Assessment (EQA) data. This includes a major workshop in Autumn 2026 involving regulators, clinicians, statisticians, and manufacturers, alongside a high-level educational report on training needs. *IVD CERSI is the In Vitro Diagnostic Centre of Excellence for Regulatory Science and Innovation*.

6. The 5-Year Roadmap: Strategic Goals

Short-Term Goals (Immediate to Year 1: 2026–2027)

- Formalise External Collaboration Pathways with the Regulators (MHRA), Accreditors (UKAS), NHS England, IVD Providers (BIVDA), Learned Societies (LabMed, RCPath, IBMS), NHS Supplies.
- Secure a concrete operating framework to interface with critical external groups who would like to work with PFLM. This will ensure that a collaborative strategy is discussed in order to ensure that a Patient-Focused Clinical Quality Management System underpins the delivery of IVDs.
- The HbA1c deep-dive identified other analytes, where performance may be sub-optimal. We have identified 'Analytes of Concern' (AoC); we will prioritise these AoC. We have set up a Task and Finish Working Group with the RCPath to define acceptable Analytical Performance Specifications for tests used in the NHS. We have already defined this for HbA1c and EQA performance of Laboratories and methods can be seen relative to the APS.
- We have already initiated discussions with NHSE, RCPath, MHRA and BIVDA of how post market performance surveillance can identify poorly performing assays and embed an infrastructure to rectify or escalate poor performing tests.
- Build structured technical groups focused immediately on analytes displaying high analytical variation and severe clinical consequences — HbA1c for diagnosis of Diabetes in association with LabMed also specifically looking at Haemoglobin (Hb) Variants in HbA1c and method-related differences in Bilirubin for paediatrics. These will be co-led by Birmingham Quality and Weqas with an aim for PFLM to fast-track standardised guidelines.
- Actionable POCT Outputs: Ensure that the outcomes of Webinar 3 directly feed into National Health Service England (NHSE) diagnostic safety frameworks for POCT, empowering community clinical teams with robust risk assessment tools. The foundation of this will be the GIRFT POCT Quality Wheel which will provide guidance to manufacturers, commissioners and providers involved in POCT outside the Hospital. Key to this is the issue of Accreditation of Out of Hospital POCT Testing.
- Engage with MHRA and the Learned Societies to ensure that, for patient safety reasons, availability of Direct-to-Consumer POCT is risk based.

Medium-Term Goals (Years 2 to 3: 2027–2028)

- Hold a 2027 National Face-to-Face Stakeholder Summit: Convene a landmark plenary summit uniting all key stakeholders identified in our 10 national recommendations—including NHS Supplies, BIVDA, UKAS, LabMed, IBMS, RCPath and the MHRA.
- Contractual Quality Framework Integration: Collaborate with NHS Procurement to incorporate life-cycle analytical performance specifications (APS) directly into commercial 'Managed Service Contracts' (MSCs). This moves procurement from a 'lowest cost per test' model to a legally binding quality framework with clear supplier liabilities during assay drift.
- Advise on effective Collaborative Commissioning of POCT outside the Hospital.
- Publication and Awareness Strategy: Translate localised UK lessons onto the national stage, providing laboratories with toolkits to audit their own assay variations (e.g., Folate, Calcium, Ferritin, Thyroid Hormones).

Long-Term Goals (Years 3 to 5: 2028–2030)

- Complete Cultural Shift to Patient-Focused Quality Management Systems (QMS): Eradicate process focused quality management systems and move towards a more clinically focused QMS. Establish a nationwide culture where laboratory directors are fully equipped with data extraction tools to monitor output-based clinical metrics (e.g., patient medians, proportions of patients above/below clinical thresholds and localised diagnostic incidence shifts).
- Global Prominence & Regulatory Harmonization: Drive international diagnostic standards by positioning the PFLM framework as a gold-standard reference template for post-market vigilance and regulatory harmonisation across Europe and worldwide.
- To embed into routine practice the following:

  1. ensure that the acceptable quality and use-case is defined so that Manufacturers and Pathology Providers understand what is acceptable for the use-case at purchase;
  2. ensure that post-market surveillance tools are in place to identify any shifts in performance;
  3. embed the National Quality Infrastructure Framework into common practice allowing collaboration between manufacturer and provider to identify and correct poor performance in a timely way, and ensure that an escalation framework is in place if poor performance continues;
  4. That the Pathology Clinical Quality Management System enables the effect of poor performance on the patient to be given the highest priority. This enables Manufacturers and Providers to put Patient Safety first and aligns with the Patient Safety agenda of the Regulator (MHRA) and the Accreditor (UKAS).

7. Strategic Alignment with the 10 National Recommendations

This strategy maps perfectly against our 10 Core Recommendations published in CCLM (2026)[1,2]:

PFLM Focus Area	Core Recommendation Alignment	Operational Mechanism
Clinical Consequences	Rec 1 &4: Understand & communicate clinical impact of assay out-of-tolerance and drift on patient pathways.	PFLM webinars to raise awareness Publications Working with LabMed for T&F WG Promotion of *LabTestsOnlineUK*
EQA & Pathology Data	Rec 2 & 3: Maximize national EQA usage and refine Analytical Performance Specifications (APS) using the Milan model.	EQA Schemes to promote clinical consequences of analytical findings identified through EQA Collaborating with RCPath to transition from 'achievable' to 'clinical utility-driven' limits for core biochemistry.
Accreditation & Safety	Rec 5: Focus ISO 15189:2022 assessments on risk management across the entire patient pathway.	Expanding technical accreditation into comprehensive clinical audits covering pre- and post-analytical phases.
Vigilance & Procurement	Rec 6, 7 & 10: Enhance MHRA Yellow Card reporting and implement post-market codes of conduct with BIVDA/ABHI.	Embedding mandatory life-cycle performance monitoring within NHS Supplies procurement contracts.
Education & Training	Rec 8 & 9: Deliver toolkits for lot-to-lot verification and host Laboratory Director Masterclasses.	Supporting LabMed to roll out standardized resources

Table 2: Cross-referencing 5-Year Strategic Focus Areas with PFLM National Recommendations.

8. Conclusion

Every single result matters, because every single result belongs to a patient.

The Patient-Focused Laboratory Medicine (PFLM) Group has demonstrated that meaningful national leadership in clinical quality can be achieved through professional collaboration, shared expertise, and a commitment to patient safety. Since its formation in late 2024, the group has successfully engaged the wider laboratory community through national webinars, influential publications, strategic partnerships, and the development of a growing network of stakeholders committed to improving diagnostic quality across the UK. These achievements have established a strong foundation for future activity and have highlighted the need for a more coordinated, patient-centred approach to laboratory quality management.

The projects currently underway, including the National Quality Census, Yellow Card Survey, POCT quality initiatives, and post-market surveillance collaborations, will provide critical evidence to inform future policy, regulation, and quality improvement strategies. Importantly, they represent the first steps towards a more integrated quality infrastructure that links laboratory performance directly to patient outcomes.

Over the next five years, PFLM aims to build upon this foundation by strengthening collaboration between regulators, accrediting bodies, professional societies, manufacturers, commissioners, and service providers. Through the development of robust analytical performance specifications, enhanced surveillance systems, and a truly patient-focused clinical quality management framework, the group seeks to embed a culture in which diagnostic quality, patient safety, and continual improvement are central to every stage of the testing pathway. Ultimately, PFLM's vision is to help establish a sustainable national framework that not only improves outcomes for patients across the UK but also serves as an international model for diagnostic quality and post-market vigilance.

9. References

[1] PFLM Group. Getting it right for the patient, are we good enough? Meeting Report with Recommendations. February 2026. https://pflm.org.uk/

[2] Marrington R, Freedman D, Housley D, Thomas A, Davies G, MacKenzie F, Myers M. Clinical quality in UK laboratory medicine: current status and what the wider laboratory community can learn. Clin Chem Lab Med. 2026 Jun 12. doi: 10.1515/cclm-2026-0575. Epub ahead of print. PMID: 42290599.

[3] LabMed News December 2025. https://labmed.aflip.in/labmed-news-december2025. Pages 12–14

[4] Mass Diabetes Diagnoses in the UK. Lessons for all labs — lessons for human and veterinary laboratories from a recently human laboratory problem. https://www.westgard.com/essays/guest-essay/diabetes-misdiagnoses-uk-lessonsl.html