hemato

MDPI

Editorial

What Is New in Computational Pathology, Spatial Biology and AI-Driven Precision Medicine

Antonino Carbone [1,*] and Annunziata Gloghini [2]

[1] Centro di Riferimento Oncologico, Istituto di Ricovero e Cura a Carattere Scientifico, National Cancer Institute, 33081 Aviano, Italy
[2] Department of Advanced Diagnostics, Fondazione IRCCS, Istituto Nazionale Tumori Milano, 20133 Milano, Italy; annunziata.gloghini@istitutotumori.mi.it
* Correspondence: acarbone@cro.it

1. Introduction

Precision medicine is entering a phase in which the principal question is no longer whether new technologies can generate biologically meaningful information, but how that information can be validated, regulated, scaled and integrated into clinical decision-making. Digital pathology, artificial intelligence (AI), spatially resolved omics and liquid biopsy have each matured rapidly, and their convergence is reshaping biomarker discovery, companion diagnostic (CDx) development and diagnostic practice.

The 21st edition of Biomarkers, CDx & Precision Medicine Europe was held at the Congress Center Basel, Switzerland, on 13–14 October 2026 [1]. Organized by Oxford Global, the meeting combined programs on biomarkers and companion diagnostics; computational pathology, AI and precision diagnostics; spatial biology for precision medicine; and, new in 2026, precision biomarkers and personalized healthcare. It was co-located with NextGen Omics, Tech & Data Europe, and also included a computational pathology hackathon, collaboration-hub discussions, and dedicated AI & Data and Start-Up zones [1,2]. Following the "what is new" format, this report summarizes the main advances and open questions emerging from the meeting, with particular attention to their implications for hematology and hematopathology.

Although most presentations used solid tumors as examples, the questions raised are directly relevant to hematology. Hematologic neoplasms were among the first areas in which immunophenotypic, cytogenetic and molecular data were integrated into diagnostic classification, and in which minimal residual disease (MRD) monitoring entered routine clinical decision-making. Lymph node, bone marrow and peripheral blood specimens are now increasingly digitized, so that the issues debated in Basel—how computational and spatial readouts can be validated, regulated and integrated into existing diagnostic workflows—apply equally to hematopathology.

2. What Is New in Precision Medicine: Beyond Oncology

A recurrent message was that the precision medicine model developed in oncology is now being extended to other disease areas. The opening keynote, "New Frontiers in Precision Medicine: the Neurology Example", discussed how omics, imaging, digital biomarkers and AI can be combined to link molecular stratification with clinically meaningful endpoints in neurological disease—a persistent gap in neurological drug development [1]. The same theme recurred in a session on Alzheimer's disease that combined AI with cell-free DNA methylation profiling and in a spatial biology session that compared lessons

Check for updates

Received: 22 October 2026
Accepted: 26 October 2026
Published: 28 October 2026

Copyright: © 2026 by the authors. Licensee MDPI, Basel, Switzerland. This article is an open access article distributed under the terms and conditions of the Creative Commons Attribution (CC BY) license.

learned in Alzheimer's disease and in oncology [2]. In parallel, a regulatory perspective on personalized medicine addressed the extension of the CDx paradigm beyond oncology [1].

3. What Is New in Computational Pathology

Computational pathology was one of the most extensively represented areas of the program. The emphasis was clearly placed not on the performance of individual algorithms but on the conditions required for their clinical deployment.

3.1. Foundation Models, Large Language Models and Agentic AI

A dedicated panel addressed the challenges of deploying pathology foundation models, large language models (LLMs) and agentic AI in pathology workflows, and a further session examined the use of foundation models in clinical trials and CDx development [2]. Foundation models, pre-trained largely by self-supervised learning on very large collections of whole-slide images (WSIs), generate reusable tissue representations that can be adapted to many downstream tasks with limited additional data. The discussions focused on generalizability across scanners, staining protocols and institutions; on computational cost; and on the difficulty of validating models that are trained for one purpose and repurposed for another.

3.2. Histology-Derived AI Biomarkers and Their Regulation

Several presentations treated the hematoxylin and eosin (H&E)-stained slide as a quantitative data source rather than only a morphological record, including "Decoding Tumor Histology With AI To Personalize Cancer Treatment" and "The Role of Histology-Derived AI Biomarkers in Multimodal Cancer Treatment Decision Making" [2]. These approaches extract prognostic and predictive information that goes beyond conventional morphological assessment. A complementary session on the regulatory considerations for "computational precision biomarkers" highlighted the new questions raised when an algorithm itself becomes the diagnostic test: how analytical validity should be established, whether models should be locked or allowed to evolve, and how such tools are to be evaluated under the European In Vitro Diagnostic Medical Devices Regulation (IVDR) [2].

3.3. From Validation Frameworks to Global Deployment

Implementation was addressed at several levels. An academic hospital presented an institutional framework for the clinical validation of digital pathology tools, providing a practical model for governing the adoption of AI from local validation to routine diagnostic use [2]. A pharmaceutical perspective addressed the scaling of AI-driven image analysis from digital pathology to precision medicine, and other sessions covered AI-based characterization of the tumor microenvironment (TME), open approaches to biomarker discovery and CDx development, and hybrid models that combine global networks of expert pathologists with purpose-built algorithms developed for pharmaceutical partners [2]. On the second day, a roundtable on "Globalising Computational Pathology" considered the prerequisites for the worldwide adoption of digital and AI-assisted pathology: infrastructure, laboratory digitization, reimbursement, interoperability and equitable access in resource-limited settings [1]. A start-up presentation on privacy-preserving AI within a deployed digital pathology platform addressed the data-protection constraints that currently limit multi-institutional model development [2].

3.4. Implications for Hematopathology

Hematopathology poses specific challenges for these tools. Diagnosis typically integrates morphology with extensive immunohistochemistry (IHC), flow cytometry, cytogenetics and molecular genetics, so that models trained on H&E images alone capture only part of the diagnostic information. Small core needle biopsies, decalcified bone marrow trephines and heterogeneous fixation add pre-analytical variability, a major source of the limited cross-site generalizability discussed at the meeting. Conversely, several high-volume, standardized tasks—differential counts in bone marrow aspirates, quantification of marker-positive cells and screening of lymph nodes for involvement—are natural candidates for early, well-validated AI assistance under pathologist supervision. Multimodal models combining images with immunophenotypic and molecular data are likely to be required for most diagnostic questions in this field.

4. Classic Hodgkin Lymphoma as a Paradigm for AI-Assisted Diagnosis

Within the computational pathology program, one of the authors presented "Diagnosing Classic Hodgkin Lymphoma in the Era of Artificial Intelligence" [2,3]. Although cHL is highly curable and its diagnostic criteria are well established, it remains challenging for AI: Hodgkin and Reed–Sternberg (HRS) cells are rare (0.1–10% of cells, frequently less than 1%), the core markers are not disease-specific, and the entity overlaps with mediastinal gray zone lymphoma, Epstein–Barr virus (EBV)-driven lymphoproliferations and nodular lymphocyte-predominant B-cell lymphoma. Interobserver variability also makes the "ground truth" used for supervised training uncertain. The proposed response is an AI-augmented ecosystem that combines pathology foundation models, weakly supervised detection of rare HRS cells and quantitative analysis of the TME, and returns a probabilistic diagnosis with a calibrated confidence score and explicit flagging of ambiguous cases for expert review [3]. Realistic near-term roles include standardized PD-L1 scoring and macrophage quantification, HRS cell highlighting and case triage, provided that models are externally validated according to standards such as TRIPOD+AI and PROBAST+AI. AI was presented as an evolution of pathology, not its replacement [3,4].

5. What Is New in Spatial Biology

The spatial biology program reflected a field in rapid maturation. Sessions ranged from immuno-oncology ("From Space to Spatial: Shaping Cancer Immunotherapy with Spatial Omics") to autoimmunity, including spatial transcriptomics of salivary glands, and to neurodegeneration [2]. The dominant theme was translation: presentations on moving "from spatial discovery to clinical translation" and on spatial biology at production scale illustrated the shift from exploratory tissue atlases toward reproducible, decision-relevant readouts [2]. Technology-oriented sessions compared region-of-interest strategies with whole-slide high-plex imaging, including a practical evaluation of a whole-slide multiplex immunofluorescence imaging platform, and they presented automated multiplex imaging workflows designed to improve throughput and reproducibility [2]. Speakers repeatedly emphasized that spatially resolved signatures will become clinically useful only when they can be measured robustly and compared across sites, and when they are integrated with routine histopathology. This is directly relevant to lymphomas, in which neoplastic cells are often admixed with abundant reactive cells. In cHL, for example, the proximity and organization of immune cells around HRS cells, and not only their abundance, appear to carry biological and prognostic information [3]; comparable spatial readouts could complement conventional immunophenotyping in other lymphoma entities.

6. Generative AI and Virtual Staining: An Emerging Frontier

The second-day keynote, "From Data to Design: AI-Driven Generative Biology and the Future of Personalized Medicine", described a conceptual shift from AI as an analytical tool to AI as a generative engine capable of proposing molecules, hypotheses and interventions [1]. Generative modeling of tissue images is also the conceptual basis of virtual staining, in which immunohistochemical or multiplex-like information is computationally predicted from H&E-stained or label-free images. Although virtual staining was not the subject of a dedicated session, it lies at the intersection of the computational pathology and spatial biology programs, and the central concerns of the meeting—cross-site generalizability, validation of computational biomarkers against established reference methods, and regulatory evaluation—apply directly to it. For rare cell diseases such as cHL, the fidelity with which virtual stains detect scattered neoplastic cells will be a particularly stringent test. In hematopathology, potential benefits include tissue sparing in small lymph node core biopsies and bone marrow trephines, in which material for additional immunostains and molecular studies is often limited; before any diagnostic use, however, virtual stains will need to be validated against conventional IHC in multicenter series.

7. What Is New in Biomarkers, Companion Diagnostics and Regulation

The biomarker and CDx program focused on integrated testing strategies. One presentation outlined an approach to global precision oncology that combines tissue and liquid biopsy, digital pathology, comprehensive genomic profiling and MRD monitoring [1]. Another addressed somatic genomics—that is, mutations acquired over a lifetime—as a source of disease insight and of therapeutic targets [1]. Regulatory specialists from industry and contract research organizations addressed CDx development under the IVDR, and panels on AI-enabled clinical trial innovation and on AI in non-clinical safety assessment examined how AI might reshape trial design, patient selection and endpoint definition, while emphasizing that the path to regulatory acceptance remains long [1,2]. For hematology, the integration of MRD assessment into multimodal testing strategies is particularly relevant: MRD measured by flow cytometry or molecular methods is already embedded in the management of several hematologic malignancies, circulating tumor DNA is being explored for response assessment in lymphomas, and the regulatory questions raised for CDx under the IVDR apply equally to these assays.

8. Future Directions

The main themes discussed at the meeting, the advances presented and the challenges that remain are summarized in Table 1.

Five priorities emerged. First, validation is now the rate-limiting step: robust, multicenter and regulator-ready evidence is needed to move AI tools from feasibility to practice. Second, the routine H&E slide is becoming a quantitative biomarker platform through histology-derived AI biomarkers and, prospectively, virtual staining. Third, spatial biology is moving toward the clinic but requires standardization, automation and integration with routine pathology. Fourth, precision medicine is expanding beyond oncology, with neurology and autoimmunity as leading areas. Fifth, computational pathology will fulfill its promise only if digitization and AI tools are accessible beyond a small number of well-resourced centers. For hematology, these priorities translate into the need for multicenter, digitized collections of lymph node, bone marrow and blood specimens annotated with integrated diagnostic data, and for prospective studies testing AI and spatial tools within existing diagnostic and MRD workflows.

Table 1. Key themes from Biomarkers, CDx & Precision Medicine Europe 2026: what is new and what remains to be solved.

Theme	What Is New	Remaining Challenges	Relevance for Practice
Precision medicine beyond oncology	Omics, imaging, digital biomarkers and AI linked to clinical endpoints in neurology; CDx concepts extended beyond oncology	Biomarker–endpoint linkage; regulatory pathways outside oncology	Biomarker-guided stratification in non-oncological diseases
Foundation models, LLMs and agentic AI	Reusable tissue representations; foundation models proposed for clinical trials and CDx	Generalizability across sites and scanners; validation of repurposed models; computational cost	Faster development of task-specific tools from limited data
Histology-derived AI biomarkers	H&E slide used as a quantitative source of prognostic and predictive information	Analytical and clinical validation; IVDR evaluation; locked versus adaptive models	Additional information from routine slides without extra tissue
Clinical implementation	Institutional validation frameworks; scaling in pharma R&D; global deployment initiatives	Infrastructure, reimbursement, interoperability, equitable access	Governance of AI adoption in pathology departments
Spatial biology	From discovery atlases to production-scale, translational readouts; whole-slide high-plex imaging; automation	Standardization, cross-site comparability, integration with routine histopathology	Spatial immune metrics as candidate prognostic and predictive biomarkers
Generative AI and virtual staining	AI shifting from analysis to design; stains predicted from H&E or label-free images	Fidelity for rare cells; validation against conventional IHC; regulatory status	Potential tissue sparing and faster turnaround
Classic Hodgkin lymphoma	AI-augmented ecosystem with probabilistic outputs and ambiguity flagging	Rarity of HRS cells, label noise, lack of external validation	Triage and HRS cell highlighting under expert review

9. Conclusions

Biomarkers, CDx & Precision Medicine Europe 2026 showed a field in transition from technological demonstration to clinical implementation. AI, pathology foundation models, spatial biology and generative approaches such as virtual staining are reshaping how tissue-based information is generated and interpreted, but their clinical value will depend on rigorous validation, standardization and regulatory alignment. Hematologic neoplasms, in which diagnosis already integrates morphology, immunophenotype and molecular data, are a natural field for this transition, and classic Hodgkin lymphoma, with its rare neoplastic cells and complex microenvironment, illustrates both its promise and its requirements. Throughout, the pathologist remains central as the integrator of morphology, biology and data.

Author Contributions: Conceptualization, A.C.; writing—original draft preparation, A.C. and A.G.; writing—review and editing, A.C. and A.G. All authors have read and agreed to the published version of the manuscript.

Funding: This research received no external funding.

Data Availability Statement: No new data were created or analyzed in this study.

Acknowledgments: The authors thank the organizers of Biomarkers, CDx & Precision Medicine Europe 2026. During the preparation of this manuscript, the authors used Claude (Anthropic, San Francisco, CA, USA; Opus 5.5) for English editing. The authors have reviewed and edited the output and take full responsibility for the content of this publication.

Conflicts of Interest: A.C. was an invited speaker at the meeting. The authors declare no other conflicts of interest.

Abbreviations

The following abbreviations are used in this manuscript:

AI	Artificial intelligence
CDx	Companion diagnostic(s)
cHL	Classic Hodgkin lymphoma
EBV	Epstein–Barr virus
H&E	Hematoxylin and eosin
HRS	Hodgkin and Reed–Sternberg
IHC	Immunohistochemistry
IVDR	In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746
LLM	Large language model
MRD	Minimal residual disease
TME	Tumor microenvironment
WSI	Whole-slide image

References

1. Oxford Global. Biomarkers, CDx & Precision Medicine Europe 2026. Available online: https://oxfordglobal.com/precision-medicine/events/biomarkers-precision-medicine (accessed on 19 October 2026).
2. Oxford Global. Biomarkers, CDx & Precision Medicine Europe 2026—Agenda. Available online: https://oxford-global.com/precision-medicine/events/biomarkers-precision-medicine/agenda (accessed on 19 October 2026).
3. Alibrahim, M.N.; Carbone, A.; Gloghini, A. How artificial intelligence may solve diagnostic and prognostic challenges in classic Hodgkin lymphoma. *Blood Rev.* **2026**, *77*, 101390. [CrossRef]
4. Alibrahim, M.N.; Carbone, A.; Gloghini, A. Predictors of sensitivity to immune therapies in classic Hodgkin lymphoma. *Blood Neoplasia* **2026**, *3*, 100207. [CrossRef] [PubMed]

Disclaimer/Publisher's Note: The statements, opinions and data contained in all publications are solely those of the individual author(s) and contributor(s) and not of MDPI and/or the editor(s). MDPI and/or the editor(s) disclaim responsibility for any injury to people or property resulting from any ideas, methods, instructions or products referred to in the content.