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„We need a turning point for cancer medicine"

>> Oncology and haematology are at a turning point in 2025. Cancer is on track to become the leading cause of death across Europe by 2030. Decades of medical progress, technological leapfrogging innovations and a substantial expansion of specific treatment principles and combined therapy methods have raised cancer medicine to a new level. However, the healthcare system is often unable to keep pace with this positive dynamic - because the system that is supposed to absorb these innovations and make them accessible to everyone was conceived when molecular diagnostics, personalised medicine and demographic ageing were still foreign concepts. The crucial question is: **How do we ensure that innovative therapies actually reach patients across the board and in a sustainable manner?**

Clinical research between innovation and gaps in care

Clinical research is the foundation of modern cancer medicine. It enables early access to medical innovations and brings progress directly to patients.

However, the full realisation of this potential is hindered by fundamental systemic hurdles that set Germany back in international comparison as a research location. Complex bureaucratic processes with lengthy authorisation procedures, a dense regulatory landscape and inconsistent reimbursement practices hamper the rapid implementation of new therapeutic approaches. At the same time, the inadequate and fragmented data and digital structure is a key obstacle. There is still no comprehensive, nationwide, pseudonymised patient database - a core infrastructure that has long been called for by science, industry and patient representatives. It is essential in order to efficiently identify suitable patient cohorts for clinical studies and generate valuable real-world data for healthcare research.

These systemic deficits have far-reaching consequences: Germany is losing considerable speed and attractiveness in the international competition for clinical research, which is increasingly impairing the country's ability to drive medical progress. Medical progress also remains a privilege of urban regions: More than 20% of German counties do not have an active study centre, and innovative therapies such as CAR-Tsare regionally limited. These structural challenges are further compounded by the lack of decentralised study structures and an acute shortage of specialists, which affects both qualified clinical staff and experienced study coordinators. Although researching physicians could benefit enormously from the rapid development of qualifications and direct access to medical progress, the considerable additional organisational effort is a deterrent, leaving valuable expertise unused. For patients, these deficits often lead to insurmountable organisational barriers that make access to life-saving studies significantly more difficult.

Important legislative steps have been taken with the Health Data Utilisation Act (GDNG) and the Medical Research Act (MFG) to facilitate data exchange and remove regulatory hurdles. However, these approaches, as well as intensive efforts for the more comprehensive and standardised use of register data, are still in the implementation or establishment phase. Only the consistent removal of further regulatory hurdles and sustainable digitalisation will create the framework in which clinical research and care can develop their full potential. In everyday clinical practice, there is still a lack of automated, intelligent information on study availability, and user-friendly registers for patients to actively participate in studies are still in their infancy. In principle, the chances of improvement are good due to Germany's enormous strength as a research nation.

This potential stems from our outstanding scientific basis and a traditionally strong research community, which continues to establish Germany as an extremely attractive location for clinical research. The scientific infrastructure is excellent: university hospitals and specialised centres enjoy an international reputation, and the quality and depth of clinical data enable state-of-the-art studies at the highest level. The close cooperation between academic research, specialised laboratories and industry promotes forward-looking impulses and the development of innovative therapeutic concepts for cancer medicine. This impressive combination of strengths, which once made Germany one of the world's leading research centres, underlines the immense but currently underutilised potential of medical research.

Healthcare itself is also a challenge: even with the privilege of exemplary rapid market access in Germany, it has not yet been possible to fully and efficiently integrate innovations into everyday healthcare. This is because the true quality of cancer medicine is not only measured by the availability of state-of-the-art therapies, but also by their seamless integration into comprehensive everyday patient care. Although active substances are often reimbursable in Germany just 17 days after EMA authorisation, the actual transfer into widespread practice is considerably delayed. This is due to the fact that the efficiency of the quality of care is largely determined by the speed and flexibility in dealing with evidence-based guidelines, the consistent use of data and continuous health services research. Guidelines that provide certainty and orientation for therapy decisions must be regularly adapted to new findings and their use must be documented transparently - a process that is often lengthy and varies from region to region, further delaying the use of innovative therapies. This systemic delay can have serious consequences for those affected. Especially in cancer medicine.

Access to optimal cancer medicine therefore requires rapid and actively driven translation in particular: healthcare research must analyse the enormous amount of data collected in a targeted manner and feed the results back into healthcare in order to quickly identify and

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close gaps. The prerequisite for this is that the focus is expanded from pure product authorisation to the entire treatment pathway in order to create a networked, learning system that adapts dynamically to new findings and needs. Digitalisation plays a decisive role here as a catalyst: cross-sector platforms, structured standards and digital solutions can harmonise data flows, accelerate processes and improve communication between all stakeholders. Initiatives such as the DKG project EDIUM show how practice-relevant, data-based quality analyses can promote implementation and how research, guidelines and care can be more closely interlinked so that progress actually arrives where it is most urgently needed: directly with the patients.

Oncological care in Germany is at a crossroads

Oncological care in Germany is facing multiple challenges that go far beyond the aspects of research integration already discussed and require a fundamental realignment of the system architecture. In addition to rising costs and a projected deficit of 6.2 billion euros for statutory health insurance, the profound demographic change is also putting our healthcare system to the test.

Together with the specialist departments in hospitals, the cross-sectoral care provided by our haematologists and oncologists in private practice (NHO), who treat around 500,000 patients close to their homes every quarter, forms an indispensable foundation. This continuous chain of care, from complex interventional procedures to outpatient drug-based tumour therapy, is invaluable for patients.

However, the reality of healthcare is proving to be structurally fragmented, which makes it difficult to consistently implement medical progress. Critical interfaces - for example between primary care and specialist centres - are often characterised by inefficiency, which leads to delays and communication problems. This lack of integrated care pathways is also dramatically exacerbated by the acute shortage of specialists. Even in this situation, digital processes, the reduction of administrative tasks and the targeted opening up of roles for care and assistance professions are not just options, but rather mandatory prerequisites for securing and further developing care.

A comparison with international benchmarks - including Denmark and the Netherlands - reveals the urgency of a fundamental system reform: a quality-focused concentration of care in specialised, certified centres, supplemented by digital pathways and clear management rules, demonstrably improves outcomes and patient satisfaction. This illustrates the central management deficits in the German healthcare system, which are also evident in the implementation of the National Cancer Plan. Although this was a conceptual milestone, it is not fully effective in its implementation. Responsibilities for key care objectives are not clearly assigned and there is no binding framework that brings together research, care and control in a systematic performance review. In comparison, we fall short of the standards that France, Sweden and the EU have convincingly demonstrated with clear budgets and evaluable care pathways.

Against this background, the promising approaches of the planned structural reforms in the hospital and primary care system are not sufficient if they only reinforce existing structures. Although they can deploy resources in a more targeted manner, direct patient flows based on evidence and integrate complex cases into highly specialised structures, there is a risk that access routes will be made more difficult for vulnerable groups due to classifications or regional inequalities. The solution requires accompanying, intelligent measures: flexible organisation, drop-off and pick-up services and increased cross-sectoral digital communication.

We need a fundamental new level of governance that effectively brings together evidence-based research, responsibility and resources. This is precisely where the proposal for a National Cancer Council comes in - as an independent steering body with equal representation. It would organise funding and resource allocation transparently, structure the integration of innovation and healthcare research and provide binding support for the implementation of key healthcare objectives. Such a council should openly, transparently and strategically steer the implementation of the National Cancer Plan and the sustainable financing of all measures. With regular evaluation, course corrections and the exchange of experience from pilot projects and international benchmarks, it can anchor effective care concepts nationwide. In close coordination with the steering group and with the involvement of all relevant stakeholders, innovations, new models and prevention become standard and care is modernised in the long term.

Realising the full potential of modern cancer medicine requires the constructive and equal cooperation of all relevant stakeholders: from industry and politics to science and care, self-administration and patient representatives. Only through such joint and forward-looking management can evidence-based decisions, equity of care and strategic innovation be elevated to the guiding principles of cancer medicine as a whole - as the foundation of a genuine intergenerational contract in the healthcare system.

Germany has all the basic prerequisites for this: a top infrastructure, committed research and strong networks. However, the transformation to modern, fair and future-proof cancer medicine will only succeed with the courage to undertake structural reform, the consistent prioritisation of added value for patients and genuine transparency for all those involved. This is the turning point that we must now shape together. <<