Overview: Objectives and measures

Topic	Objective	Measure
I Stakeholder networking and support	1) Ensure coordinated implementation of measures in the National Strategy	1) Establish a governance structure to implement the National Strategy
	2) Strengthen political accountability for GCTs – a key topic for the nation's future	1) Prepare an annual progress report on the National Strategy for GCTs
		2) Implement intra-annual measures to convey successes of the national network for GCTs to political stakeholders at federal and state level
		3) Organize information events for policymakers at innovation locations
		4) Establish and maintain contact with German representatives on EU bodies and committees
	3) Strengthen national networking structures	1) Establish a central point of contact (GCT website) with structured information about all stakeholders
		2) Design and compile a national GCT map depicting relevant stakeholders, structures and other parties, along with their functional interactions
		3) Conduct analysis of network components and the links between them, plus subsequent SWOT analysis
		4) Raise profile of GCT network-related issues in the national science community; organize network events
	4) Establish and expand national and international networking activities	1) Provide information for national and international patient advocacy groups
		2) Provide information for patients
		3) Provide information for international/European clinical research groups
		4) Establish an exchange of information with national and international regulators
		5) Appeal to national and international investors and funding providerss
		6) Exchange and cooperate with public-private partnership (PPP) initiatives, especially the EU's Innovative Medicines Initiative (IMI)
		7) Provide targeted information for scientific organizations and associations
		8) Raise the profile of the GCT initiative at international scientific congresses
		9) Establish an exchange of information with medical service providers and health insurance funds
		10) Integrate international entities into the GCT value chain
II Training and development of skills	1) Establish training and development programs for early career professionals and specialists, and improve the necessary infrastructure for training and development	1) Create and implement a concept for multi-track, modular additional training
		2) Establish extra-occupational, interdisciplinary Master's and doctoral programs at universities and universities of applied science (FHs) along with training programs for all occupational groups in the field of GCTs
		3) Establish national GCT education and training centers to strengthen academic, non-academic and industrial skills
	2) Develop adequate career concepts, bonus concepts and interaction concepts	1) Create incentive systems, bonus systems and career concepts
		2) Develop an interaction concept to support training and career development for relevant stakeholders

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III Technology transfer	1) Improve the framework for early identification and utilization of innovative potential of scientific results	1) Education, training and development
		2) Strengthen technology transfer offices (TTOs)
		3) Establish structures for the targeted implementation and market preparation of GCT projects
	2) Ensure comprehensive consultancy and assessment of transfer projects, incorporating the entire development process from production of an IMP to its use in patient care	1) Establish a product development unit (PDU) to support project planning and implementation
		2) Create and operate jointly accessible infrastructure for GCT developers
	3) Facilitate efforts to exploit the social and/or economic potential of scientific results	1) (non-GCT-specific): Develop national guidelines for transparent spin-off standards, e. g., based on the USIT Guide
		2) (GCT-specific): Clarify and improve the framework so that start-ups in the initial phase can use existing infrastructure at their (parent) research institute, especially cost-intensive GMP infrastructure
		3) (GCT-specific): Conduct patent research and analysis for a small number of select and definitive key technologies
	4) Establish recognition of transfer activities and successes in translation as part of individual researchers' and institutions' scientific reputations	1) Optimize academic incentive systems and project-specific employment conditions for qualified staff members
		2) Communicate technology transfer success stories
		3) Make transfer activities a quality criterion for research institutions
IV Standards, norms and regulatory framework conditions	1) Defragment and standardize responsibilities and processes in the clinical research and development of GCTs, and strengthen the federal higher authority and its resources as a single point of contact	1) Implement uniform standards and processes for issuing a manufacturing authorization, particularly in the context of GCTs and their starting materials and active ingredients, by adjusting the allocation of responsibilities between local authorities and the Paul-Ehrlich Institute (PEI)
		2) Strengthen the PEI with sufficient resources
		3) Consolidate and integrate the different approvals processes for the development of medical devices and in vitro diagnostics, including their software, into the existing application and authorization procedure for clinical trials on medicinal products in accordance with Regulation (EU) No 536/2014 (CTR) and the central authorization process set out in Regulation (EC) No 726/2004
	2) Continuously adapt regulatory processes to developments in the field of GCTs	1) Establish a central GCT-GMP and regulatory affairs committee
		2) Extend master file systems to GCTs
		3) Develop and introduce a regulatory "sandbox"
		4a) Foster an open-ended discussion on the current ATMP definition and relevant regulatory pathways for adoptive cell therapies with genetically modified cells (e. g., CAR-T-cell therapy)
		4b) Reform of the German Stem Cell Act (StZG)
		5) Establish a register for hospital exemptions to increase transparency and success measurement
	3) Improve the availability of low-threshold regulatory advice	1) Establish a low-threshold regulatory advice service

Topic	Objective	Measure
V Quality and capacity of GMP production	1) Promote the establishment and expansion of qualified GMP infrastructure (manufacturing and quality control capacities) in line with demand, for starting materials and complex GCT products	1) Create a central GCT-GMP and regulatory affairs committee
		2) Collect data on academic and commercial GMP infrastructure that already exists, is being planned or is under construction in Germany. Compare this against data for Europe and determine the need for GMP infrastructure for GCT manufacturing and quality control
		3) Secure sufficient funding from the federal government, state governments and other providers to establish, expand, maintain and operate GMP infrastructure based on demand
		4) Create a central national production facility to manufacture critical starting materials for GCTs
	2) Secure the necessary staffing capacity and expertise for GCT manufacturing and quality control	1) Expand and professionalize education and training for qualified staff in all areas in GMP production of GCTs
		2) Improve the framework for employment to attract and retain qualified specialists in the field of GCTs
	3) Increase the efficiency and speed of manufacturing processes	1) Establish a clearly structured database with manufacturing-related information and documents that is accessible for all stakeholders
		2) Create a shared basis of knowledge and communication by utilizing repositories with standardized data storage and access
	4) Pursue continuous development and risk-based streamlining of framework conditions	1) Perform risk-based harmonization and streamlining of statutory and regulatory requirements for GMP-compliant manufacturing and control
VI Research and development	1) Improve the structural conditions for translational research and development	1) Establish a national GCT network with hubs
	1) Identify and promote topics for the future	1) Establish new, flexible funding formats, with a short lead time, which meet needs that are currently not given due consideration
	3) Improve the organizational and regulatory framework for pre-clinical and clinical GCT studies	1) Facilitate the implementation of GCT manufacturing processes and their translation into early clinical studies
		2) Promote acceptance of animal experimentation and encourage the realistic assessment of potential alternatives
		3) Measuring and publication of performance indicators for regulators and supervisory authorities
		4) Optimize and refine ethics committees
	4) Ensure that patients, patient advocacy groups and patients' associations are duly involved	1) Define standards for project budgets and remuneration for patient advocates
		2) Develop specific interaction concepts
	5) Foster a change in mentality and bolster bio-entrepreneurial spirit in the German GCT community	1) Foster the necessary shift in mentality regarding GCTs
		2) Offer natural scientists career prospects and positions as bio-entrepreneurs in the public sector

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VII Marketing authorization and transition to patient care	1) Facilitate access to patients and their targeted selection for specific GCTs	1) Develop and implement education and advanced training programs to ensure optimal diagnostics to identify and stratify patients and to monitor courses of treatment for standard care facilities
		2) Establish interdisciplinary therapy decision boards as the gold standard in GCT diagnostics
		3) Create nationally harmonized qualification criteria and standards for GCT access diagnostics and monitoring of disease progression
	2) Increase flexibility of reimbursement and care models in the use of GCTs	1) Employ the best available evidence for the assessment of additional benefits
		2) Amend the criteria for consideration of medical care-related data in benefit assessments
		3) Substantiate benefit-based price-setting
		4) Increase the use of performance-based reimbursement models in central price negotiations
		5) Standardize and ensure cost coverage for diagnostics-related reimbursement
		6) Create more flexible reimbursement models in the financing of quality assurance/care
	3) Provide high-quality, safe and efficient treatment for patients with innovative therapies by establishing interdisciplinary GCT treatment facilities	1) Establish close structural interaction between research and healthcare
		2) Streamline the processes necessary for qualification and certification to administer GCTs in treatment facilities
		3) Streamline contract design procedures
		4) Ensure efficient assignment and communication between the personnel and institutions involved in treatment
	4) Optimize and establish the data landscape to ensure the versatile usability of this data in research and facilitate long-term GCT data	1) Standardize the acquisition and storage of treatment data
		2) Establish a method-specific national GCT register
VIII Interaction with society	1) Inform society about GCTs by providing reliable, target group-specific information	1) Establish a central communication platform with an online presence to provide information for different relevant target groups
		2) Create or refer to target group-specific information resources for the general public
		3) Create or refer to target group-specific information resources for media representatives/ journalists
		4) Create or refer to target group-specific information resources for patients and patients' organizations
		5) Create or refer to target group-specific information resources for pupils, students and teachers
		6) Create or refer to target group-specific information resources for medical expert associations
		7) Offer a regular newsletter for patients/organizations/expert associations on relevant GCT publications and activities
	2) Support/advise decision-makers by strengthening engagement with politics and facilitating/ maintaining an open-ended humanistic/social discourse	1) Improve the targeted communication of information to political stakeholders
		2) Establish/maintain an open-ended humanistic/social discourse
	3) Implement targeted measures to promote the potential benefits of GCTs through increased involvement and participation of research funding organizations, foundations and parts of civil society willing to donate	1) Identify and map research funding organizations, foundations and private donors
		2) Develop specific information material for foundations and private donors willing to contribute and organize high-profile events to attract donations by securing funding specifically dedicated to knowledge transfer
		3) Strengthen established and/or planned funding measures and their synergistic development together with foundations and private donors willing to contribute