SkinTERM Policy Brief: Advancing Regenerative Skin Therapies in Europe for Wound Care

Unlocking the Future of Wound Healing through Strategic Investment in Research & Training

SkinTERM Horizon 2020 project July 2025

Executive Summary

The **SkinTERM project** has made significant advances in the field of regenerative skin therapies. By exploring novel biomaterials, cell-based skin substitutes, and human skin organoids, the project has laid the scientific and technological foundation for **next-generation treatments** that go beyond wound closure to promote **true skin regeneration**, including restoration of pigmentation, sensation, and thermoregulation.

These innovations have the potential to **dramatically improve outcomes** for patients suffering from burns, chronic wounds, and post-surgical problems - while also reducing the **long-term healthcare costs** associated with complications, hospital stays, and secondary treatments.

We urge the European Commission and national health authorities to accelerate clinical adoption, integrate findings into treatment guidelines, and support reimbursement pathways.

The successful translation of these breakthroughs into clinical care now depends on addressing several systemic challenges:

- **Insufficient interdisciplinary training** to support the next generation of regenerative medicine professionals;
- **Fragmented and complex regulatory frameworks**, particularly for combination products and cell-based therapies;
- **Lack of dedicated funding mechanisms** for cross-sectoral translational research;
- **Capacity bottlenecks** in medical device certification under the EU MDR.

To translate the results to advance regenerative skin technologies for patients, and deliver societal and economic benefits, we call for **targeted investment** in:

- Translational research and clinical validation of biomaterials and cell therapies;
- Interdisciplinary education and workforce development;
- Regulatory streamlining and support for innovative skin substitutes;
- Public engagement and ethical guidance for advanced technologies like skin organoids.

The Context and Problem

Skin injuries pose a major clinical and economic burden on healthcare systems in Europe. Management can be complex across primary and hospital settings. Current treatments, including autografts and synthetic dressings, have significant limitations including

- donor site morbidity
- poor cosmetic outcomes
- risk of infection
- high costs

There is an urgent need for more effective, scalable, and personalized skin regeneration therapies.

Scientific Advances and Innovation Potential

New ingredients for acellular dermal templates

By studying the matrisome of wound healing (in axolotl, spiny mouse *Acomys cahirinis* and foetal human cells), SkinTERM has identified/further established important extracellular matrix (ECM) molecules and effector molecules that play a role in regenerative wound healing. These molecules show great potential as components of next-generation dermal templates.

Action Point: Support translational R&D to incorporate these findings into clinically viable, pro-regenerative wound care products.

Cell-based skin replacements with improved functionality

The incorporation of specific cell types, e.g., melanocytes, hair-follicle derived cells, or cells of the neurovascular plexus, into cultured autologous keratinocyte and fibroblast layers on biodegradable matrices, can convert wound healing towards regeneration with enhanced functionality, such as skin colour, UV protection, hair formation, sensation and thermoregulation.

Action Point: Fund **comparative and preclinical studies** evaluating different cell types and matrix combinations to accelerate clinical translation.

Human skin organoids as a model of skin development

SkinTERM developed long-term (>100 days) human organoids with a multilayered structure and containing sebaceous gland-like structures. Such organoids provide models that may be used to study skin development, reconstruct appendages, test drugs and toxicological effects, and study skin disorders.

Action Point: Provide long-term funding, infrastructure, training and regulatory guidance for **ethical organoid research**, with particular attention to developing **these tools for clinical translation**.

Implications for Policy and Healthcare

Our findings could represent a ***paradigm shift in wound care.*** They offer a novel scientific platform and effective treatments, with and without personalisation.

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Implications for Healthcare and European Policy

Potential for human applications: Targeted research is needed that translates SkinTERM's findings into practical, clinically effective therapies for improving human health. By focussing on strategies that promote improving wound care and reducing scarring, this should enhance the quality of life for patients, especially those with severe injuries or undergoing surgeries. These efforts support broader public health goals by advancing patient-centred care, reducing complications, and improving long-term outcomes.

Healthcare cost reduction: Effective wound healing solutions that **reduce scarring and restore skin function** could have the potential to **significantly lower long-term healthcare costs**, particularly in the treatment of burns and other skin conditions. To fully understand the economic value of these innovations, **early health technology assessments (HTAs)** should be conducted. These evaluations are essential for informing **public health budgeting and resource allocation**. While the SkinTERM project has demonstrated scientific and preclinical potential, **HTAs were not performed** and should be prioritised in future research phases to guide investment and implementation strategies.

Issues related to Improving Wound Care Research in Europe.

Wound care in the European Union presents a growing public health and economic challenge, with significant variation in quality across and within Member States. Limitations in treatment are driven by budget and expertise constraints, and a lack of suitable interventions. These issues lead to preventable patient harm and a burden on healthcare systems[1].

Key Societal Issues

- Inconsistent Care: Quality of care is uneven, influenced by treatment availability, local care access and resources. Complications e.g. surgical wound infections increase risks.

- Population Impact: The prevalence is 3–4 people per 1,000 (≈1.5–2 million people in EU27). Treatment consumes 2-4% of EU healthcare budget[2]. Surgical wound infections affect 30–40 per 1,000 surgeries, leading to ~5% excess mortality.

- *Demographics:* In 2024, the population aged 65+ was over 20% of the EU population and continuing to grow[3]. The risk and burden of wounds are strongly linked to aging. Research-led interventions and evidence-based policy planning and design of interventions must account for this rising burden.

- Growing Market Size and Scale: The European Advanced Wound Care Market is estimated to be USD 4.22 billion in 2025 and growing to USD5.68 billion by 2030, a CAGR of >6%[4]. This contributes to Europe's globally competitive innovative Medtech sector.

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Sector Innovation and Research Needs

- *New interventions and treatment options:* SkinTERM has pioneered new approaches that offer opportunities to address the shortcomings in current treatment options and address unmet clinical needs for better wound care and treatment. There is still a need for investment in improved wound management and effective treatments.
- *Stronger clinical and real-world evidence:* Building on improved preclinical methods, improved clinical trials and real-world data are needed to evaluate cost-benefits of wound care treatment.

- *Cost and Quality:* Evidence shows that better training, early diagnosis, appropriate treatment selection, and referral protocols can improve patient outcomes and reduce healthcare costs. Systematic *Health Technology Assessments (HTAs)* and better use of Patient Reported Outcomes should assess cost-effectiveness of innovations, and support reimbursement and policy decision making.

[1]Eucomed. The Burden of Wounds on EU Healthcare Systems; [2]Woulgan (2023). *Health Economics of Wound Care in Europe.*[3]Eurostat 2024; [4]www.mordorintelligence.com;

Regulatory Support for Skin Substitute Therapies

Innovative skin substitutes, with or without cells, hold strong potential for wound care but face delays due to complex and unclear regulatory pathways. These products typically fall under the Medical Device Regulation (MDR) or the Advanced Therapy Medicinal Products (ATMP) Regulation, yet many sit in a grey area between the two. While EMA offers classification support, uncertainty remains—especially for combination products—slowing development and approval.

The MDR has introduced new bottlenecks, including a shortage of notified bodies and increased documentation, leading to product delays or withdrawals and reduced patient access. The ATMP framework is also highly complex, particularly for smaller or academic developers, due to overlapping rules and high compliance burdens. Innovative skin substitutes, both with and without cells, offer significant potential in wound care, but their development is often hindered by **complex and unclear regulatory pathways**.

To address these challenges, policy makers should:

- Provide **clear classification guidance** for skin substitutes
- **Expand notified body capacity** and streamline documentation for proven products
- **Simplify ATMP pathways**, potentially through a **single-window system**

Improving regulatory clarity and efficiency is essential to accelerate access to safe, effective therapies for patients across Europe.

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Strategic Call to Action

Improving wound care is essential for sustainable healthcare in the EU. Standardized care, provider training, timely and improved interventions are key strategies to improve patient outcomes and reduce system-wide costs

SkinTERM has shown that regenerative skin technologies are no longer speculative—they are emerging realities. But without focused policy action, their journey from bench to bedside will remain slow and uncertain.

We call on **European and national policymakers**, funding agencies, and regulatory bodies to:

- **Prioritize regenerative medicine in upcoming research and innovation frameworks;**
- **Facilitate interdisciplinary collaborate efforts at the European level;**
- **Invest in cross-sectoral training, clinical trials and infrastructure;**
- **Streamline regulatory processes for faster clinical translation;**
- **Develop and fund EU-wide best practice guidelines for wound care;**
- **Promote early diagnosis and referral systems to prevent complications;**
- **Ensure ethical oversight and public support for novel biotechnologies for wound care.**

By acting now, Europe can lead the global effort in transforming wound care, while improving quality of life and ensuring sustainable healthcare systems.

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