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# *Integrative healthcare challenges and the emergence of convergence in Nanomedicine: from health sciences to health care*

Abstract (Calibri 8)

Nanomedicine is bringing converging sciences to healthcare through an adequate platform of technologies allowing new horizons for better health care. It also enables innovation both in the design of clinical research and the clinical use to face unmet clinical needs.

Advances brought by nanomedicines in oncology and infectious diseases are now expanding both within these clinical areas and also looking at their use to previously unmet clinical needs. The advances in the last five decades of basic research and the last 30 years of clinical practice with nanomedicines, will certainly allow for significant improvements in the next phase. This will be sustained by both solid basic research and an increased amount of clinical data compiled across different technologies and therapeutic areas.

New developments are allowing the introduction of both personalized medicine and combination therapy as drivers for innovation in clinical practice with nanomedicines. Meanwhile, current developments in the research landscape of nanomedicines brought the attention to the fact that, as an already well established area of clinical practice, nanomedicines now face also some relevant questions previously also addressed by new chemical entities and biologicals.

The innovation in materials science has to meet the challenges of clinical standards already established for already approved medicinal products. Dozens of nanomedicines went through the challenge of regulatory approval for both clinical experiences (under clinical trials) but also for marketing authorization and routine clinical use having to face the need to demonstrate both safety and efficacy but also compliance and effectiveness in routine clinical use.

New challenges arising from current debate within Regulatory Science will have to be met by better integration between advances in materials science and translational issues like validation of adequate models (i.e. preclinical human cells and tissues in appropriate setting to foster clinical translation and better outcomes within clinical phase). Targeting adequate disease stage and disease evolution conditions are at forefront of priorities trying to address appropriate personalized medicine issues.

Regulatory framework in Europe and elsewhere is currently adjusting to new realities and incorporating the best scientific standards, in anticipation of the regulatory needs both to follow-on products, combination products and integrative platforms bringing together therapy and diagnostics.

## References

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