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Commentary submitted to Nature Nanotechnology.

On the issue of transparency and reproducibility in nanomedicine

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Nano(bio)medicine offers new healthcare paradigm opportunities, and many clinical products already exist. Accurate experimental reporting and analytical/ characterization is critical for all science and it is important to not overstate the potential issues for 'nano' research; for example, within its guidance documents (1) the "FDA does not categorically judge nanomaterials or the application of nanotechnology as intrinsically benign or harmful." The need for robust assessment is clear, but the case for special attention is not obvious. Maintaining high standards is required for all disciplines, but the need for sub-field-specific checklists is unclear as best practice is already established for the disciplines contributing to nano(bio)medicine; indeed, the scientific community readily identifies poor science through peer review. In line with best practice, we recommend:

- At least two characterization techniques as no single technique can fully characterize a disperse nanoparticle sample.
- Characterization of stored samples as nanomaterials are known to change during storage.
- Inclusion of more than two nanomaterial comparators as publications often rely on limited nanomaterial diversity.
- Standard incubation techniques for tissues and cells to minimize nanoparticle interactions with plastics.
- Capturing observable safety concerns to identify nano-specific toxicities as cytotoxicity studies alone have limited value.
- Reduction in animal use for publishing purposes.

The responsibility for scientific/publication credibility lies squarely and correctly with scientists, the community in the rigour of its peer review and journal editors in their lack of acceptance of hype and claims that are not evidence-based.

Ref. 1. *FDA's Approach to Regulation of Nanotechnology Products* (FDA, 2018);
<https://www.fda.gov/scienceresearch/specialtopics/nanotechnology/ucm301114.htm>