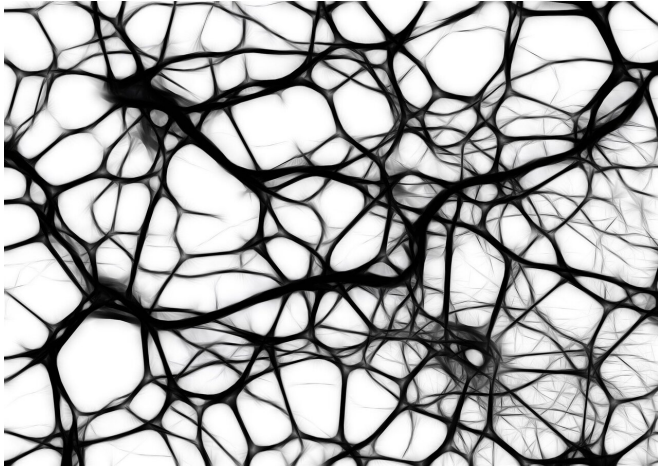


# A quality control framework for umbilical cord blood-sourced allografts

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The recent study from Burst Biologics challenges existing standards and outlines future safety and potency benchmarks.

The prestigious peer-reviewed journal *Regenerative Medicine* has announced the publication of the original research article from Burst Biologics (ID, USA) entitled, "Characterization of an [umbilical cord blood](#) sourced product suitable for allogeneic applications." The article provides a comprehensive overview of the quality attributes, clinical suitability and efficacy of BioBurst Rejuv, an umbilical cord blood (UCB)-sourced allograft, defined as a tissue graft from a donor of the same species.

Previous research has demonstrated that UCB contains cytokines and growth factors, components that are integral to bone consolidation and tissue repair.

"This current study addresses the unmet need for a uniform quality control framework to determine

clinical suitability and safety of cord blood allografts," said Christopher D. Jones, CEO of Burst Biologics and a corresponding author of the paper. "This is the first known published report enumerating the tests to address identity, purity, safety and potency for a UCB sourced allograft."

The study reports on exosome-based therapy, which may be the next quantum leap in [regenerative medicine](#), a field focused on replacing or regenerating [human cells](#), tissue or organs, to restore or establish normal function. The published article identifies a unique liaison among the UCB-sourced allograft, host [mesenchymal stem cells](#) (MSCs) and their secreted [exosomes](#) that influences tissue regeneration in vivo.

"Based on these findings, clinical suitability of cord blood allografts must account for the non-cellular components while evaluating their promising role in tissue regeneration," stated Jones. "This study brings us one step closer to optimizing the bounds of regenerative medicine."

In the study, the identity of BioBurst Rejuv was established by use of flow cytometry, a [mass spectrometry](#)-based proteomic approach and protein multiplexing testing. Microbiological screenings, graft-versus-host disease testing, and endotoxin values were used to assess safety and purity.

The non-cellular components were found to be effective in promoting cell proliferation, migration and neutralizing redox-stress in vivo and MSCs treated with a UCB-sourced allograft demonstrated boosted potential for [tissue](#) regeneration. The UCB-sourced allograft was also found to be functionally stable up to 2 years when stored at optimum conditions.

"Burst Biologics has been pioneering research and product development since its inception," said Jones. "We are committed to exploring the unique

attributes of UCB components and developing future applications that improve lives."

**More information:** Mukta S Sane et al.

Characterization of an umbilical cord blood sourced product suitable for allogeneic applications, *Regenerative Medicine* (2019). DOI: [10.2217/rme-2019-0058](https://doi.org/10.2217/rme-2019-0058)

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