

Table 7: Considerations for Alternate Delivery Routes - Challenges and Opportunities

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SCOPE:

The most practical method of delivering proteins still fundamentally remain as either intravenous (clinical setting) or subcutaneous (self-administration) due to complex challenges associated with delivery of a macromolecule by non-invasive methods. In this roundtable, the discussion will be focused around non-standard delivery methods (oral, pulmonary, etc.) and factors that need to be considered when designing molecules with non-IV product profiles. First, an overview of this area will be discussed; this will be followed by an analysis on the major gaps in this field and perspectives around requirement, recent progress, potential as well as challenges associated with delivering a protein therapeutic via alternative routes.

QUESTIONS FOR DISCUSSION:

1. What is the practical outlook of delivering a protein therapeutic by non-IV-SC route?
2. Peptides have attracted a lot of attention and focus as a modality that can be delivered orally, what are some of the challenges and experiences?
3. Designing molecules for alternative delivery routes - what is the relative importance of the molecule design (protein engineering) vs. choosing the appropriate enabling strategy (formulation)?