Characterization of A Subcutaneous Bleb Model

Team 29: **Jordan Barker, Thomas Settelmayer**
Technical Advisor: **Edward Tang (Takeda Pharmaceuticals)**

Subcutaneous large volume infusions play a critical role in drug therapies that require continuous delivery at low dosages. Delivered into adipose tissue underneath the epidermis and dermis, subcutaneous injections provide many advantages over intravenous administration, including offering the possibility of at-home treatment, reducing user error and reducing overall care costs. Despite these advantages, subcutaneous administration of large volume infusions can lead to the formation of blebs that produce concentrated pressure, further leading to complications for patients receiving treatment. When utilizing subcutaneous injection volumes greater than 1 mL, these complications from bleb formation can include injection pain, high subcutaneous back pressure, leakage and reactions at the injection site. Current research on the formation of subcutaneous blebs is primarily performed through costly and laborious animal studies. Furthermore, these animal studies generally lack in providing sufficient quantitative data for analysis. To solve the issues associated with conventional animal studies, a three-part in-silico computer model was developed by Takeda Pharmaceuticals with the goal of assessing the contributing factors in predicting patient complications from bleb formations. The current computer modeling relies on the assumption that human subcutaneous tissue is a uniform space, which is not representative of real-world data and was unable to reproduce in vivo testing results. By conducting ex vivo studies utilizing proprietary subcutaneous modeling, we propose research guided solutions to flaws associated with Takeda's current computer model. Results of the conducted ex vivo studies are ultimately leading to more robust in silico modeling, capable of providing a novel and efficient alternative to in vivo testing of large volume infusion therapies.