

A Tale of Two Molecules

What's the best path for your low soluble molecule?

Two molecules, both designed to treat the same condition, both with solubility challenges.

Two biopharma companies racing to be first. Biopharma A chooses to move into trials as quickly as possible, while Biopharma B decides to address broader solubility concerns first. Who gets to market first may surprise you.



A Selects Solubility Vendor Based on Price

Believing it will save time and money, Biopharma A uses a solubility vendor for a low initial price and quick, one size fits all formulation.

B Solves for Solubility Sooner

Biopharma B focuses on solubility early to ensure they apply the right solution the first time. They partner with a global CDMO with deep solubility expertise. The CDMO uses a proprietary formulation design platform to help Biopharma B predict the best solubility solution based on Molecule B's unique properties.

Experiences Proof of Mechanism Failure

Because their molecule has poor bioavailability results in Phase I clinical trials, Biopharma A must reformulate the compound. This means more time, resources and money before they can advance their molecule.

✓ Tries Again

Biopharma A decides to switch solubility vendors to increase its odds of success. This requires new contracts, revalidation of methods, and reformulation.

✓ Applies Predictive Solubility

Biopharma B gets a recommended formula that is likely to promote sufficient bioavailability. They are even more pleased that their CDMO partner also has two additional formulation scenarios prepared if its recommendation doesn't perform to goal.

✓ Needs to Repeat Preclinical/Phase I

Proof of Mechanism, Part 2. Biopharma A must conduct additional animal and human trials to prove safety and efficacy of the new formulation. The molecule passes, but is now six months behind its competition.

Biopharma B works with their CDMO partner to continue formulation development for clinical trials using minimal amounts of API. Biopharma B is fully prepared for scale-up once clinical phase begins, saving time and money.

! Experiences Low Bioavailability - Again

Phase I speed bump. Despite the new formulation, Molecule A's Phase I results come back with 30% bioavailability.

! Needs to Make a Tough Decision

Biopharma A must pull precious R&D staff from another program to craft a new formulation or make the equally tough decision to sell the molecule.

✓ Achieves Proof of Concept

Biopharma B completes Phases I and IIa with minimal delays based on ample API supply and targeted bioavailability.

✓ Moves Toward Market

Ready for late-stage trials, Biopharma B, working with its CDMO partner, can move rapidly to scale-up with an eye toward commercialization. Molecule B continues to move closer to market — and patients in need — with a price premium advantage.

✋ Cuts Their Losses

The pressure on the Head of R&D and her staff becomes too much, and since Biopharma B's molecule looks like it will move into Phase IIb and III with few difficulties, Biopharma A decides to sell Molecule A to another company for a fraction of what it would have been worth had it reached Proof of Concept.

Biopharma A invested

44+

months and failed to pass Phase I.

Biopharma B invested

36

months and moved on to late-stage trials.

If you're not addressing solubility holistically from the beginning of development, you're putting your timeline — and your molecule — at risk.

Patheon Solubility Enhancement Services approaches BCS II drug substance solubility issues in a fundamentally different way that identifies the solubility enhancement technologies most likely to work before you get started.

LEARN HOW WE DO IT

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