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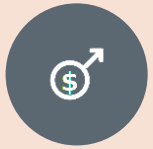
FROM PHASE 1 SCREENING TO COMMERCIAL STRATEGY

Selecting the Right ASD Technology Early

THE ECONOMIC PRESSURE HAS NEVER BEEN GREATER



Rising Costs

Drug development costs continue to climb, with late-stage delays representing the greatest losses.

Constricting Capital

Funding environments are tightening, demanding leaner, more capital-efficient development strategies.

Milestone Urgency

Pressure to hit clinical and commercial milestones rapidly with efficiency is at an all-time high.

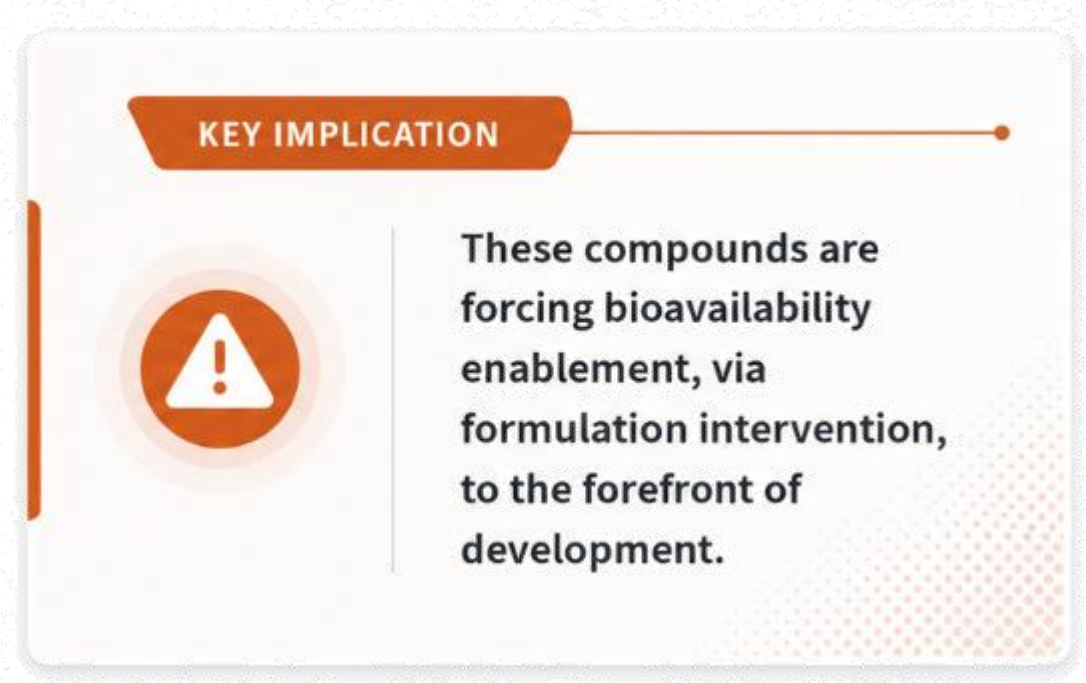
Speed and capital efficiency are no longer differentiators.

They are survival requirements.

MOLECULES ARE OUTRUNNING CONVENTIONAL DEVELOPABILITY

In-silico discovery is pushing the boundaries of chemical space. Candidates are reaching new heights of structural complexity, larger and more elaborate, with properties bordering on undevelopable.

- PROTACs
- Protein degraders
- Molecular glues
- Macrocyclics
- Peptidomimetics
- Beyond rule-of-5



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INSOLUBILITY IS UBIQUITOUS

70–90%

of molecules in modern pipelines are poorly water-soluble

Industry estimate; the solubility-limited fraction has grown steadily for two decades.

Molecular weight	Trending up
Melting point & Tg	Trending up
Organic solubility	Trending down
"Brick-dust" character	More prevalent than ever

ASDS: FROM LAST RESORT TO FIRST CHOICE

Amorphous solid dispersions were once considered a niche, high-risk approach reserved for compounds with no other options. That perception has fundamentally shifted.

FDA Approvals Surging

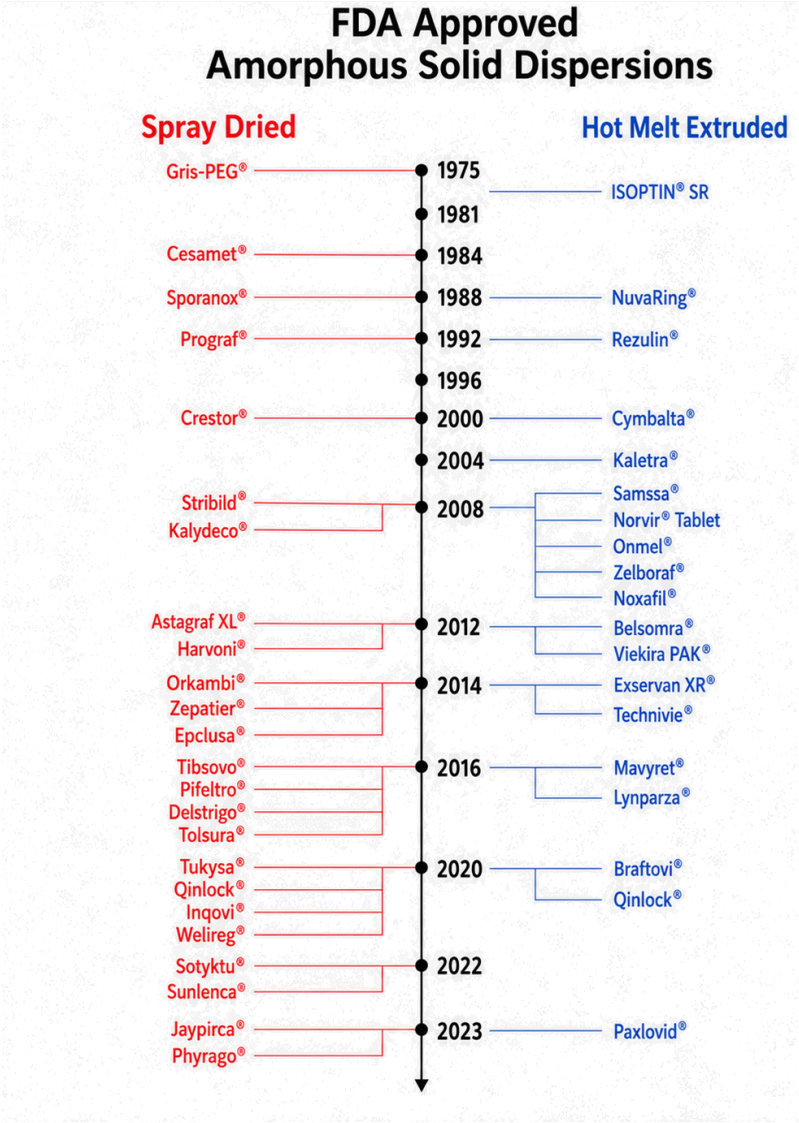
The number of approved ASD-based products has grown exponentially over the past decade, validating the technology at the highest regulatory level.

Patent & Publication Explosion

Research publications and patent filings on ASD technologies have increased dramatically, reflecting deep industry investment and scientific maturity.

Now a Development Mainstay

ASDs are the formulation strategy of choice for enabling BCS II/IV compounds. No longer a last resort, but a first-line solution driven by necessity and proven performance.



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ANATOMY OF AN ASD

ASDs range from simple binary systems to sophisticated multi-component formulations, each excipient serving a precise functional role.

Binary

Drug + Polymer. The foundational ASD system. Simple, robust, and widely used. Low IP potential.

Ternary

Drug + Polymer + Surfactant. Adds a surfactant to improve wetting, solubilization, and physical stabilization.

Multi-Component

Drug + Polymer(s) + Surfactant/Lipid + Chemical Stabilizer + pH Modifier + Flow Aids. Rare and complex. Simultaneously optimizes performance, stability, and manufacturability. Powerful drug product IP.

Polymer

Physically stabilizes the amorphous drug; concentration enhancer, precipitation inhibitor, species dictation, moisture protection.

Surfactants/Lipids

Improves wetting, enhances solubility, modifies Tg, aids solubilization and physical stabilization

Stabilizers, pH Modifiers

Anti-oxidants, chelators, pH modifiers — protect chemical integrity and tune the dissolution microenvironment

Flow aids & lubricants

Manufacturing efficiency, mass-flow enhancement, content uniformity.

The richer the excipient toolbox a technology can access, the more degrees of freedom you have to optimize.

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THE ASD TECHNOLOGY LANDSCAPE

No single technology solves every problem. *Each must be evaluated on a drug-specific basis.*

Spray Drying (SDD)

Widely utilized/commercialized and ideal for thermally labile APIs but requires specialized solvent processing infrastructure.

DESIGN SPACE

Solvent-limited

Hot-Melt Extrusion (HME)

Continuous, solvent-free process best suited to thermally stable molecules with moderate melting points but incompatible with thermally labile APIs and excipients

DESIGN SPACE

Thermally limited

KinetiSol™

High-energy, solvent-free fusion process suitable for all compound types, including the most intractable molecules. Strong IP protection. Emerging commercial presence.

DESIGN SPACE

Widest

Solvent/Anti-Solvent Precipitation (MBP)

Enables ASDs for brick-dust compounds, though scale-up and particle engineering add substantial complexity. A last-resort option.

DESIGN SPACE

Very narrow

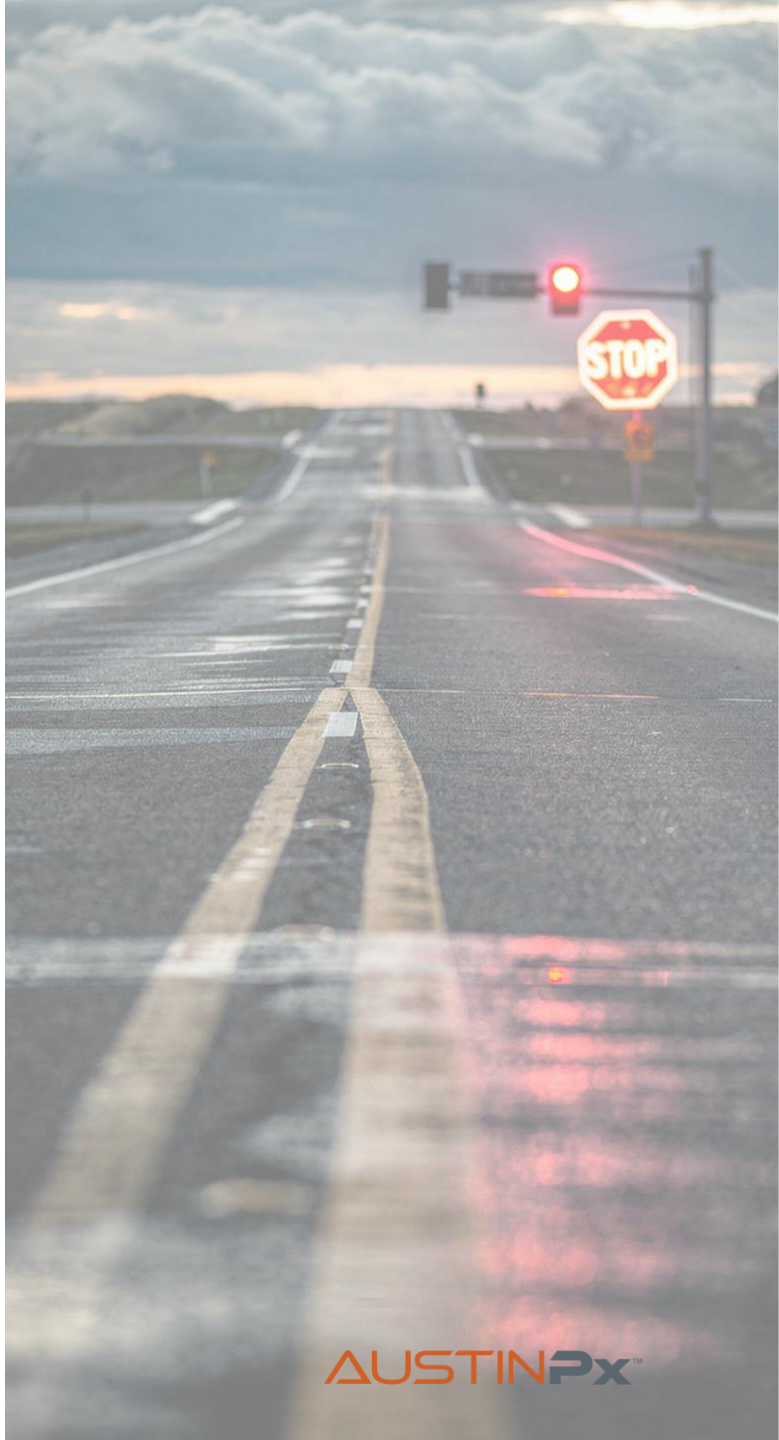
SPEED TO CLINIC VS. LONG-TERM STRATEGY

The Early Trap

A "good enough" formulation may clear early clinical milestones but carries hidden risk. Suboptimal technology choices resurface as costly liabilities in Phase 2/3, precisely when timelines and burn rates are at their peak.

The Late-Stage Penalty

Poor formulation or manufacturing process selection can trigger reduced clinical outcomes, paused studies, expensive reformulation efforts, technology pivots, human PK bridging studies, and added regulatory effort and complexity.



THE THESIS

Screen every ASD technology, up front and early.

Thoroughly and efficiently evaluate all options up front to make the best drug-specific technology selection.

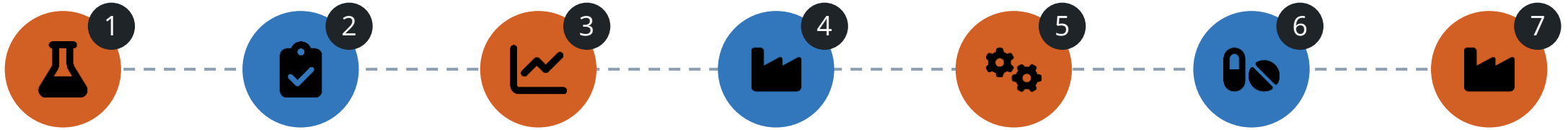
Near-term milestone achievement

Hit your immediate clinical and regulatory gates without compromise.

Long-term program needs

Protect scalability, patient experience, and commercial asset value.

WHAT COMPREHENSIVE ASD SCREENING ENTAILS



Preformulation	Binary Screening	PK & Modeling	Mfg Assessment	Optimization	Dosage Form	CTM Mfg
ASD-specific preformulation studies to frame the molecule.	Binary ASDs across all technologies; characterization, bio-relevant dissolution, accelerated stability.	In-vivo PK studies and PBPK modeling to confirm in-human translation.	Early manufacturing assessment with an eye toward long-term feasibility.	Drug-to-polymer ratios and multi-component ASDs, re-characterized and stressed.	Preclinical suspensions, clinical tablets or capsules; dissolution and stability.	GMP clinical trial material manufacture with release testing and stability support.

2–3 months | **1–2 months** | **3–4 months**

Characterization · biopharmaceutical analysis · accelerated stability recur at every stage

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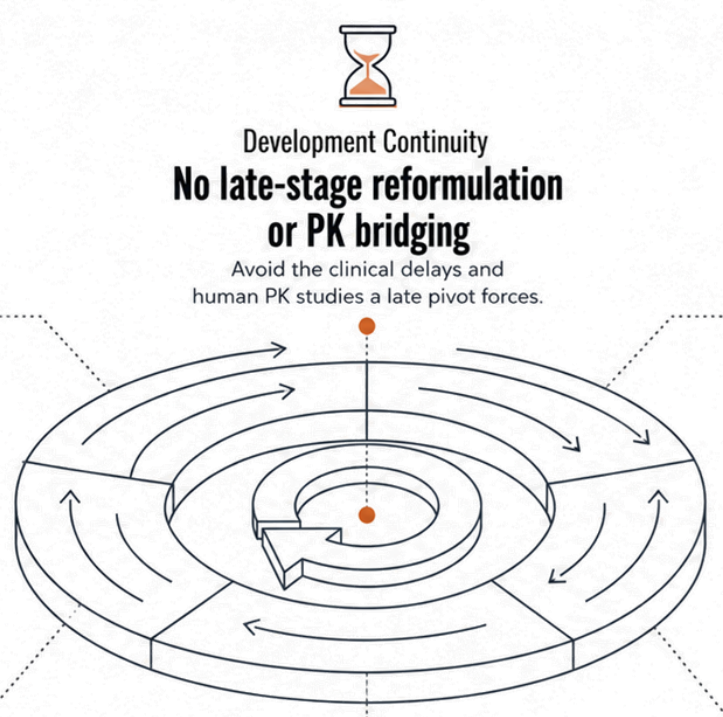
WHAT EARLY OPTIMIZATION AND THE RIGHT SELECTION DELIVER



Development Continuity

No late-stage reformulation or PK bridging

Avoid the clinical delays and human PK studies a late pivot forces.

Clinical Success

No formulation failures or clinical delays

De-risk the program before it reaches the patients and the timelines that matter most.

Process Strategy

Methods established early, improved continuously

One drug product, continuously refined, instead of a mid-stream restart.

Commercial Readiness

Line of sight to commercial

No unexpected capacity limits and no large-scale volumetric inefficiencies.

Market Access

Faster, cleaner path to market

Momentum preserved through the phases where speed is scrutinized most.

Economics

Controlled cost of goods

Avoid the ballooning COGS that a poorly chosen process locks in.

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ONE PARTNER. ALL ASD TOOLS. SPONSOR-LEVEL EXPERTISE

Spray Drying | Hot-Melt Extrusion | Co-Precipitation | **KinetiSol™**

Bioavailability Enhancement Experts

Deep, specialized expertise in amorphous solid dispersions spanning preformulation science through clinical-stage development.

Unmatched Technology Breadth

The only CDMO offering spray drying, HME, solvent precipitation, and KinetiSol under one roof, enabling true, unbiased head-to-head technology screening.

Sponsor-Side Experience

Sponsor-company history brings strategic perspective to navigate clinical, regulatory, and commercial decision points, not just formulation science.

A SUCCESSFUL LATE PIVOT

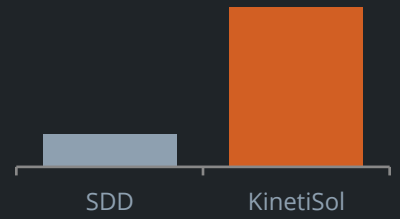
STARTING POINT: PHASE II

- Suboptimal spray-dried dispersion (SDD) and process
- Suboptimal bioavailability driving high dose and pill burden
- Risky solvent and a highly inefficient manufacturing process

The catch: *This late pivot still required two human PK studies to bridge the new formulation, a full reformulation and process redevelopment, and a CMC change package to amend the regulatory filing, costly in both time and money.*

KINETISOL™ DEVELOPMENT YIELDED

5× increase in AUC in a primate model, w/ translation to humans



Reduced dose & pill burden

Substantially improved process efficiency

Eliminated the risky solvent

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THE SAME WIN, WITHOUT THE LATE PIVOT

Had the optimum KinetiSol formulation been identified before Phase II, this program would have reached the same superior outcome without the late pivot, and everything it cost.

FASTER

to clinic and to market

No Phase II pause, no two human PK bridging studies.

Pivotal trials begin directly on the final KinetiSol formulation and process.

LEANER

total program spend

No parallel SDD, late reformulation, or process rework.

One formulation developed once and carried through, COGS controlled from the start.

SOONER

revenue recognition

No CMC change package or regulatory delay.

Market entry and revenue pull forward, and every earlier month compounds.

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THANK YOU

Let's find the right technology for your molecule, early.

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