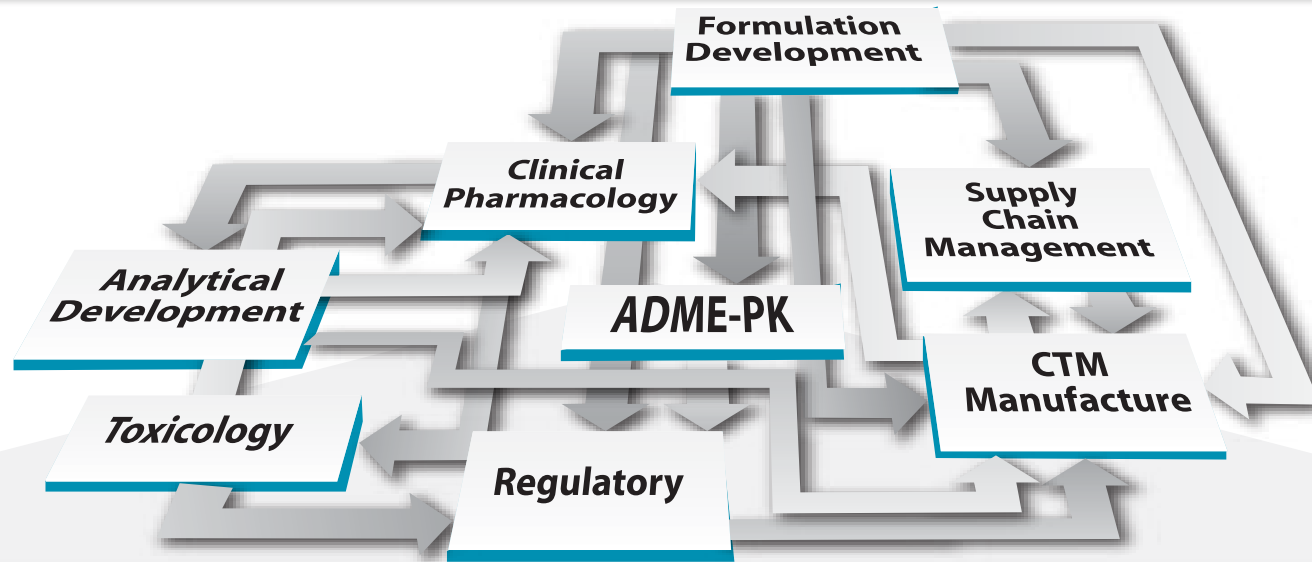


Creating an efficient drug development plan is complex.
Determining the appropriate tasks and balancing priorities vs. risk takes experience.



The PharmaDirections solution:

PathfinderTM
IND
NDA

A revolutionary tool that anticipates the complexity of a drug development program to reduce errors, surprises and changes along the journey to your IND and NDA.



To find out more, visit
PharmaDirections.com/pathfinder

5001 Weston Parkway,
Cary, NC 27513
(919) 657-0660
PharmaDirections.com



What we put into PathfINDAr™

- ✓ Knowledge of pharmaceutical experts with combined 200+ years of experience
- ✓ Cross-disciplinary expertise across all therapeutic segments
- ✓ Data engine of over 1600 lines of detailed tasks
- ✓ Industry-vetted costs specified for detailed tasks
- ✓ Dependencies, contingencies and risk factors determined based on expert analysis
- ✓ Scheduling and budget options that allow for maximum flexibility

Let PharmaDirections help you find the best path to your IND and NDA



What you get out of PathfINDAr™

- Expert analysis of YOUR unique program by industry veterans
- Detailed comprehensive drug development plan complete with risks and assumptions
- Accurate assessment of schedules and costs
- Quick turnaround of timelines, resources and gaps
- Reduced errors and surprises
- Mitigated risk
- Maximization of resources
- Plan for a path to YOUR milestones and goals

Base Project Activity Breakdown Structure (ABS)					
DATA					
ABS #	ACTIVITY	ACTIVITY DEFINITION OR QUALIFICATION	Baseline	Cost Estimate 2	Cost Estimate 3
1.0.0	General Consulting and Planning				
2.0.0	Discovery				
3.0.0	Pharm Tox (includes Tox, ADME, PK, and Animal Studies)				
4.0.0	Formulation Development & Analytical				
5.0.0	API Development and Pre-clinical Batches				
6.0.0	Quality Assurance				
7.0.0	Clinical Pharmacology and CRO				
8.0.0	Other Services				
9.0.0	Global Project Management				

4.0.0	Formulation Development & Analytical				
4.1.0	Immediate Release Tablet and Capsule Formulation				
4.2.0	Controlled Release Tablet and Capsule Formulation				
4.3.0	Nonsterile Liquid and Semisolid Formulation				
4.4.0	Sterile Liquid Formulation Development				
4.5.0	Inhalation Products Formulation				

4.2.0	Controlled Release Tablet and Capsule Formulation				
4.2.1	Formulation Assessment				
4.2.2	In Silico Formulation Development and Optimization				
4.2.3	Drug Form Selection and Pre-formulation				
4.2.4	Preclinical Development				
4.2.5	Phase 1 Development				
4.2.6	Phase 2 Development				
4.2.7	Phase 3 Development				

Pharmaceutical Development requires expertise:

- It's knowing what needs to get done
- It's knowing how to do it best
- It's knowing who can do it best
- It's knowing how to balance risk and cost

PHARMADIRECTIONS

