

Pharma/Diagnostic Partnerships in Companion Diagnostic Development

George A. Green IV, Ph.D.

**Group Director, Pharmacodiagnostic Center of Excellence
Bristol-Myers Squibb**

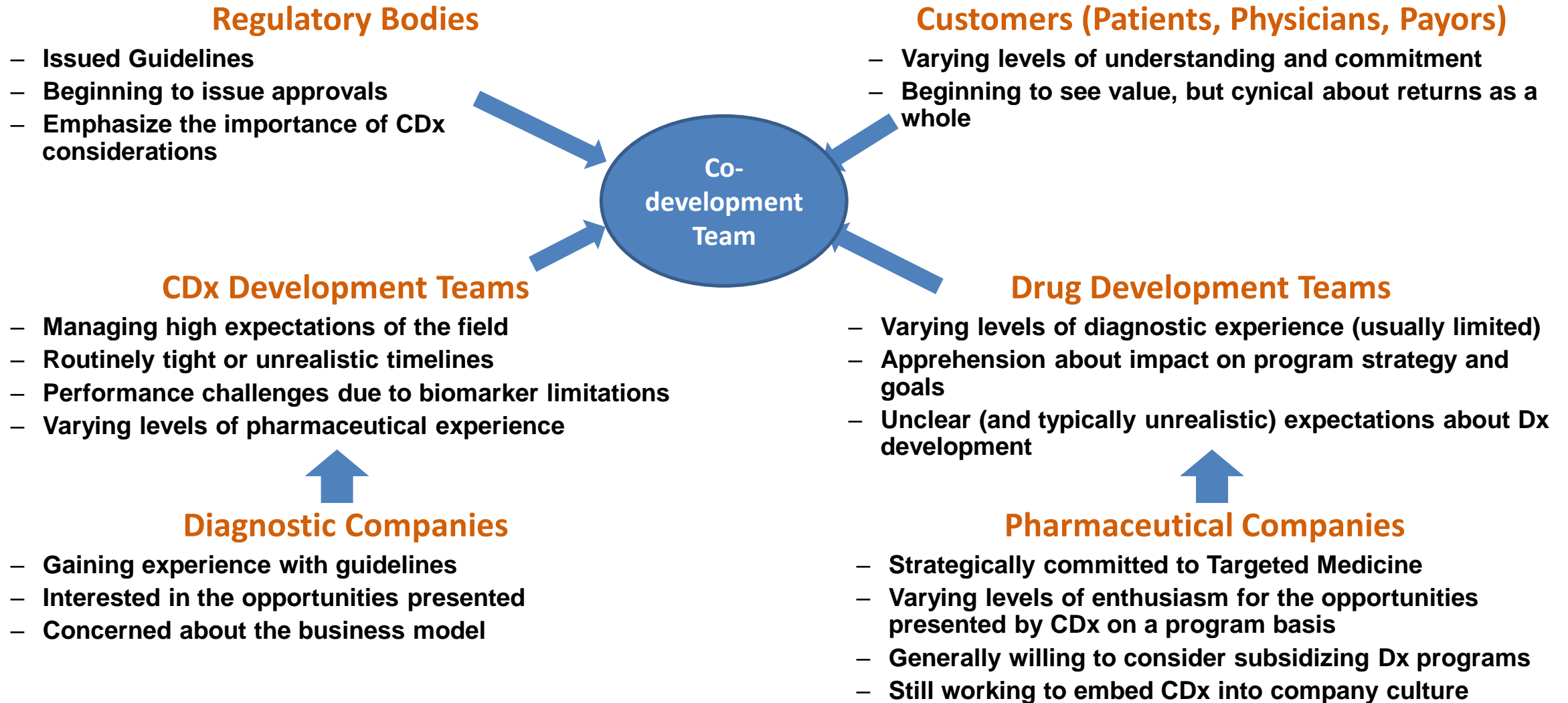
Disclaimer

- **The opinions presented here represent experiences in the field of companion diagnostics, but not the policies of Bristol-Myers Squibb**
- **The content is intended to be thought-provoking and provide considerations for managing a partnered CDx program, but is of necessity not a comprehensive list of specific details for managing such a program**

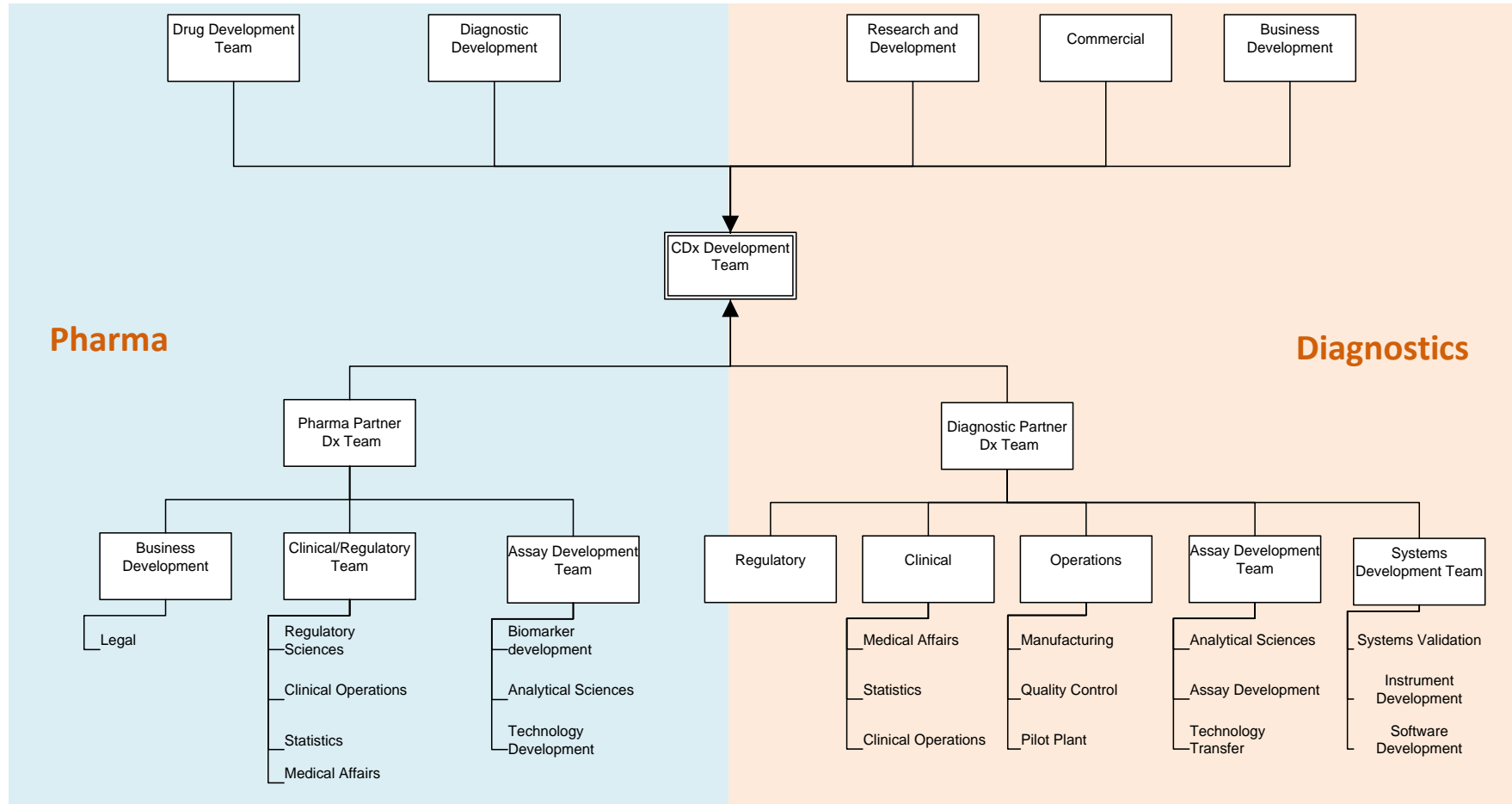
Challenges in Optimizing Pharma/Diagnostic Partnerships

- **Business models and strategies of drug and diagnostic companies are not always aligned**
- **Pharmaceutical companies emphasize**
 - No delays to drug trials
 - No limitations on drug indications
 - Alignment with drug approval schedules
- **Diagnostic companies emphasize**
 - Limited portfolio risk exposure
 - Profitability of Dx product, even if development is subsidized by Pharma
 - Requirements of QSR's and Dx regulations
- **As a result, co-development programs can be stressed by different and sometimes conflicting priorities of the two industries**

The current landscape creates disparate priorities/focus for the drug/diagnostic co-development team

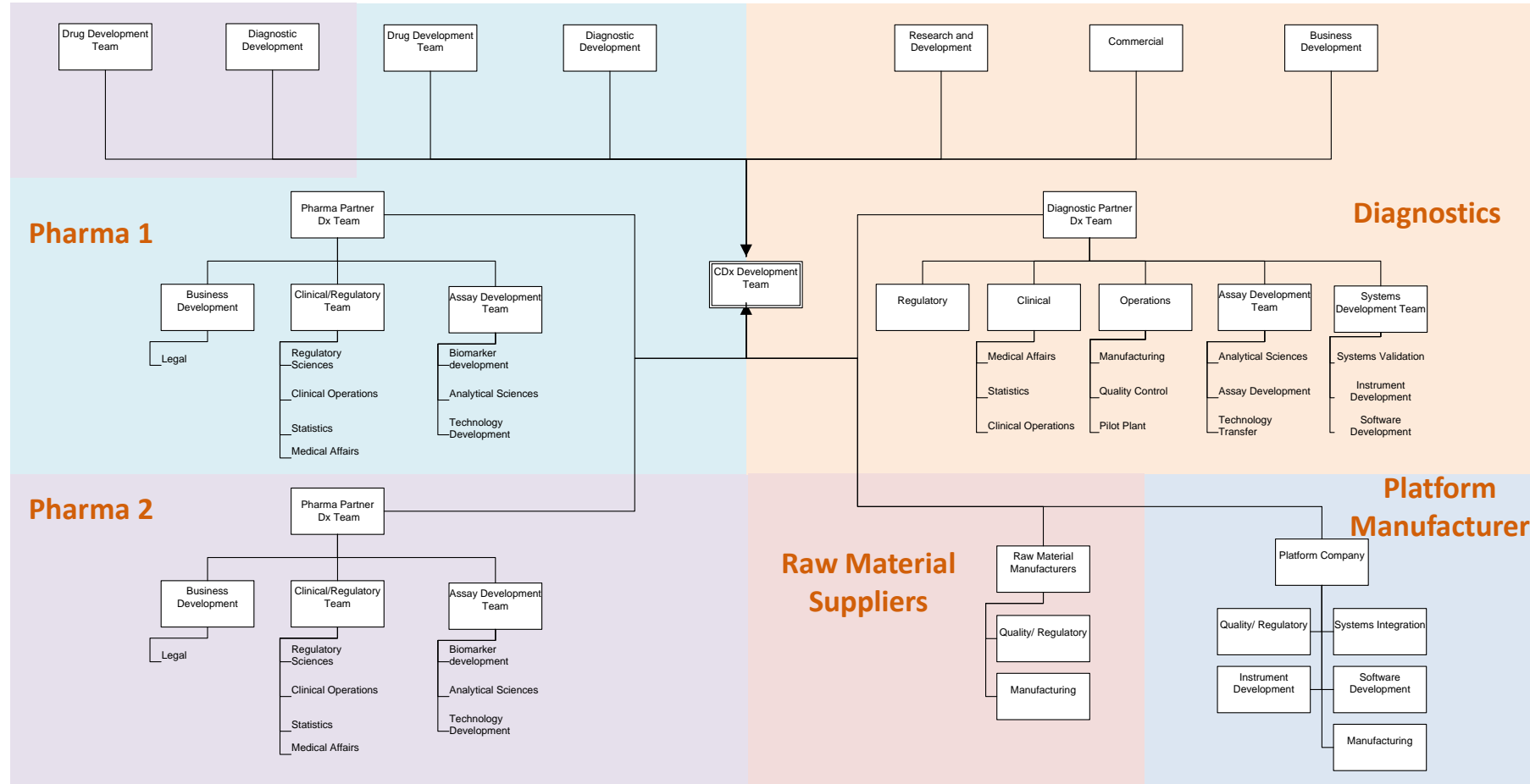


There are many players on a CDx development team



- The number of decision makers and influencers can range from dozens to >100

And the reality is probably even more complicated...



- Each company has a role with their own strategic goals, schedules, and regulatory/compliance requirements

Resolving and managing the different priorities

- **Alignment of goals**
- **Clear governance**
- **Agile and flexible working groups**
- **Effective project management (in the background)**
- **Good communication and building mutual respect for each other's capabilities and industry**

What the Contract can and can't do

- **The contract can define the relationship, manage legal, cost, and logistical issues, but it can not serve effectively as a project plan, nor can it effectively align the teams prior to their formation**
- **It should define the framework for how the project will be executed**
 - High-level program goal and milestone schedule
 - Governance framework
 - High-level division of responsibilities
 - Change management
- **The details are best left to the joint teams to work out**
 - The specific goals and scope will need to be refined as the teams develop the execution strategy
 - Detailed project plans rarely add value to the contract, as much typically changes as the execution strategy is developed

Developing program goals and scope

- **Formally defining the charter of the project team is critical**
 - Alignment on goals
 - Clearly defined scope and out-of-scope situations
 - Definition of milestones
- **However, much information is lacking at the outset of a program, and the situation may change**
 - The team must accept this and put checkpoints into the process to manage change, e.g. establishment of design requirements, conclusion of feasibility, and design lock
 - There must be governance processes defined to endorse and memorialize changes to the goals and scope
- ***Developing program goals and scope together is an effective way to initiate working relationships and mutual understanding among the joint teams***

It is important for all parties to understand each others' processes and compliance requirements

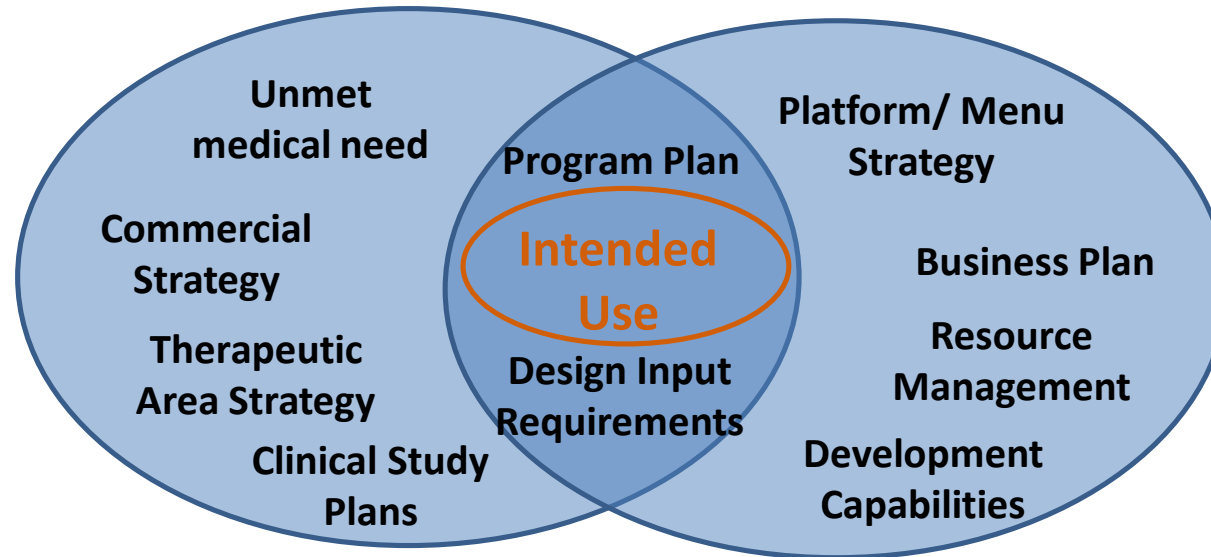
- The drug and diagnostic development processes are parallel, but not identical
- There are many international and local standards and requirements for both drug and diagnostic development. They do not necessarily coexist and align well, especially between industries.



➤ *Process overviews and expectations should be shared among the teams*

Using development milestones to build alignment

- Early discussion on a draft Intended Use for the Dx to capture how the companion products will be used together, even if ultimately it changes significantly, drives discussion of many program issues
- Compromise may be necessary; acknowledge openly where it's not possible



➤ *Developing the draft intended use is very effective at developing relationships and gaining alignment among the joint teams*

Typical Governance Bodies

- **Executive-level (e.g., Joint Executive Committee)**
 - Endorsement of strategy, program changes, issue resolution
- **Development Team (e.g., Joint Development Team)**
 - Development of program strategy, program and resource plan, budget accountability
 - Endorsement of technical development plan, clinical and regulatory strategies
- **Launch/Commercialization Team (e.g., Joint Commercialization Committee)**
 - Development of co-marketing strategy and launch plan

Sometimes a smaller group of leaders need to meet

- **Alliance management**
 - Optimize communications and manage direction of program
 - Oversee multiple programs
 - Ensure corporate-level alignment
 - **Company-focused teams**
 - Maintain focus on company's interests
 - Manage relationships, team structures both within the company and across the partnership
- *Decisions pushed down to working teams when possible to expedite mutual interests*

Potential working teams

Team	Example Responsibilities
Assay Development	Oversee technical aspects of assay design and development, execute verification and analytical validation
Regulatory	Develop and execute regulatory strategy, open line of communication with Health Authorities. Often combined with clinical team to develop strategy
Clinical	Develop final intended use aligned with clinical strategy, execute clinical validation
Intellectual Property	Ensure freedom to operate and protection of novel IP
Supply Chain	Develop and validate critical raw material manufacturing and establish raw material supply plan
Commercial	Develop co-marketing strategy, if desired. Accumulate market knowledge, develop and execute launch plan
Sample Acquisition	Develop plan to meet development, verification, and validation needs. Interface with academic, consortia, and commercial sources to acquire specimens. May merge with clinical team.

Role of Project Management

Task	Examples
Strategic Goals	<ul style="list-style-type: none"> • Program, annual
Schedule Management	<ul style="list-style-type: none"> • High level for broad team • Detailed for working teams
Resource and Cost Management	<ul style="list-style-type: none"> • Resource planning • Alignment of annual and overall budgets • Completion of milestones • Management of unexpected resource/cost demands
Communications	<ul style="list-style-type: none"> • Ensuring working teams are active and documenting results • Consistent communications through governance to all parties
First level management of issues and conflict	
Oversight of the external face of the program	<ul style="list-style-type: none"> • Publications • KOL programs • Consortia

Conclusions

- **Alignment among goals of Rx and Dx companies is a common issue that can disrupt and add major complexity to co-development**
- **The teams that execute these programs are highly matrixed across and within companies.**
 - **Active management of the teams helps ensure effectiveness in these groups of professionals likely to have many functional roles across and within companies**
- **Establishing formal governance over the program is essential but having the work done by smaller, more agile working groups helps expedite decisions**
- **Key success factors include**
 - **Alignment on common goals**
 - **Communication, trust, and relationship building**
 - **Accepting that there will be differences and working to accommodate them**
 - **Execution to plan with focus on quality**

Questions?