



Precompetitive Collaborations on Enabling Technologies for Pharmaceutical Research and Development

Enabling Technologies Consortium™ (ETC)

- AbbVie • Amgen • AstraZeneca • Biogen • Boehringer Ingelheim •
- Bristol-Myers Squibb • Celgene • Eli Lilly & Co. • Genentech •
- GlaxoSmithKline • Merck & Co. (USA) • Pfizer • Takeda •

What
is ETC?

A Forum for member companies to discuss ideas, share information, and collaborate on the development of new enabling technologies with 3rd parties such as universities, vendor companies, etc.

Who
is ETC?

Pharma & biotech companies collaborating on issues related to pharmaceutical chemistry, manufacturing, and control with the goal of identifying, evaluating, developing, and improving scientific tools and techniques that support the efficient development, and manufacturing of pharmaceuticals.

How
does ETC
work?

Discussion Phase

- Identify projects of mutual interest
- Identify SMEs & champions
- Brainstorm specific topics for focus and collaboration

Proposal Phase

- Team leads & SMEs prepare project proposals
- Evaluate project proposals
- Progress project Proposals to execution

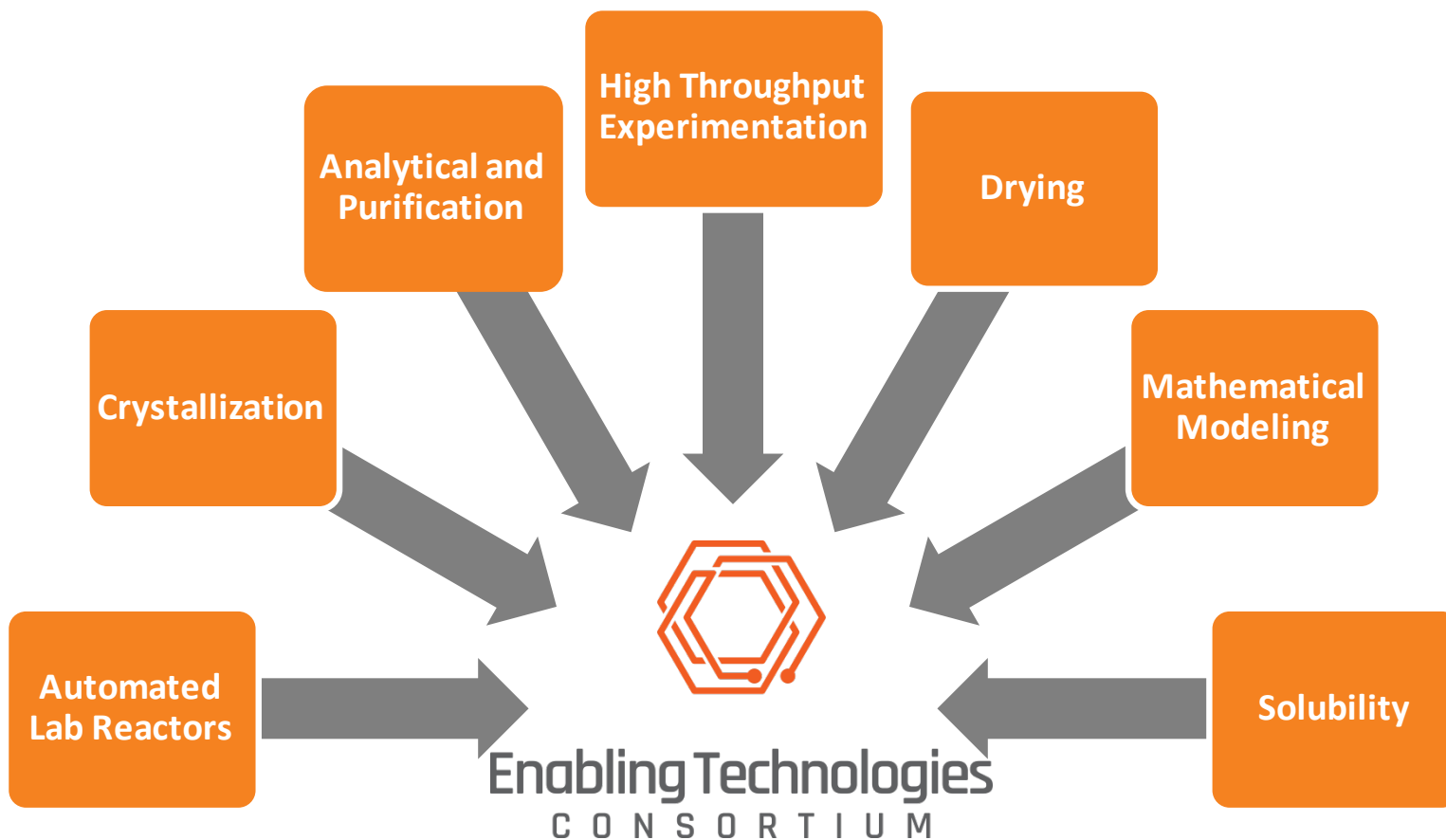
Execution Phase

- Companies jointly invest in and progress projects to execution

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www.etconsortium.org



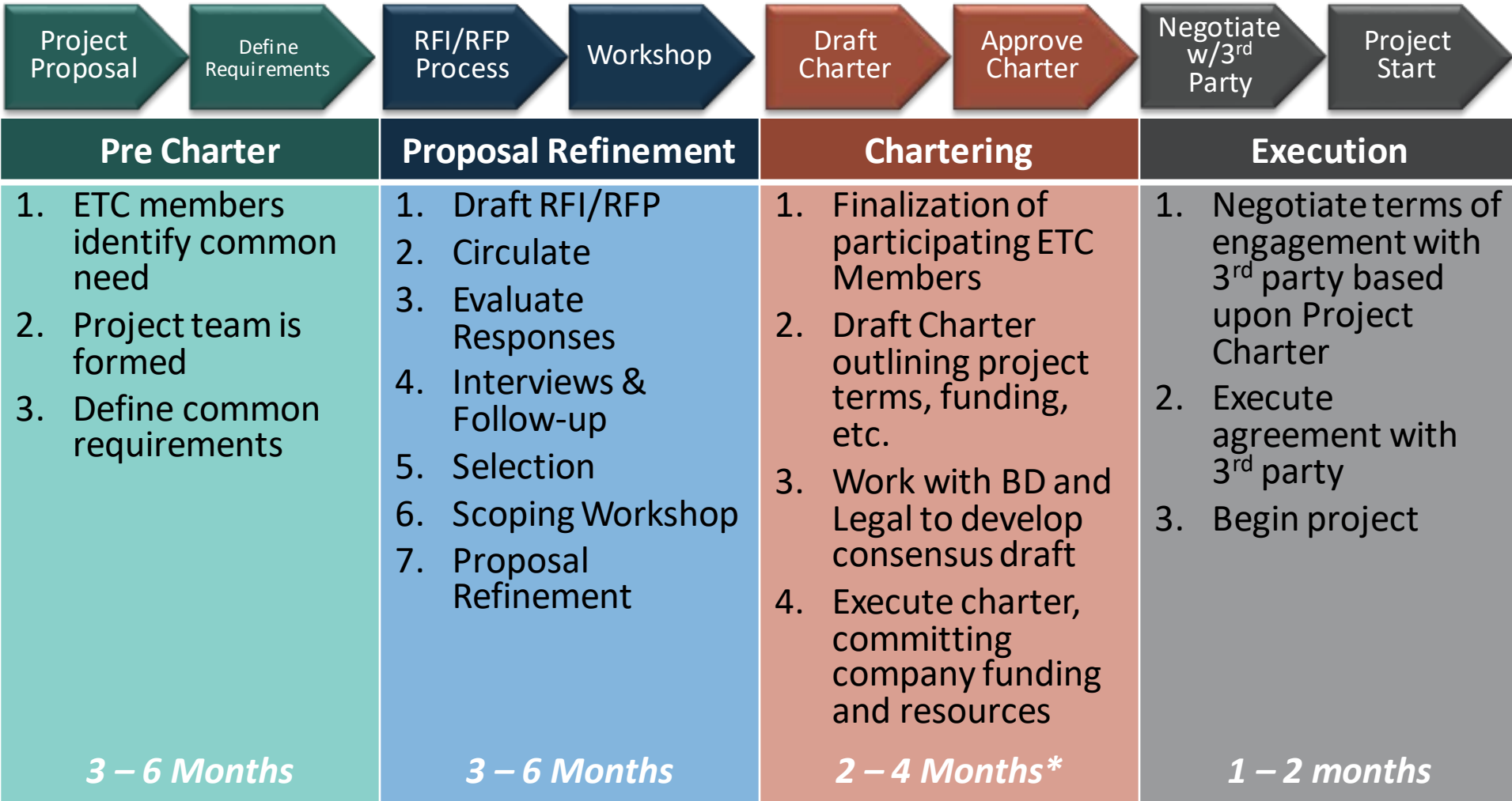
ETC Working Groups



Chairperson: Margaret Faul (Amgen)
Vice Chairperson: Jean Tom (BMS)
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ETC General Project Stages



* ETC is continuing to refine and streamline the chartering process.



ETC Current Project Portfolio

(Nov2018)

Pre-Charter
Proposal Refinement
Chartering
Execution

UHPLC-DAD w/Spectral Deconvolution	Modeling in Agitated Dryers	HT Solubility Instrumentation	Modeling SaaS Cloud	PAT Drying: Agitated Dryer Probe	Online UHPLC Sampling	Personal Parallel Reactor #1	Scale Down Dryer	Solubility Data Sharing	Semi-Prep SFC	Population Balance Model Project #1	Population Balance Model Project #2
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AbbVie	X	X	X	X	X	X	X	X	X	X	X
Amgen		X	X	X	X	X	X	X	X	X	X
AstraZeneca		X	X		X	X	X	X		X	
Biogen				X		X			X	X	X
Boehringer Ingelheim	X	X	X		X		X	X	X	X	X
Bristol-Myers Squibb	X	X		X	X	X	X	X	X		X
Celgene							X				
Eli Lilly & Co.	X	X	X		X		X	X	X	X	X
Genentech/Roche	X	X			X	X	X		X		
GlaxoSmithKline									X	X	X
Merck & Co. (USA)	X	X	X		X	X	X	X	X	X	X
Pfizer		X	X		X	X	X		X	X	X
Takeda		X	X		X		X			X	X



Shared cost + shared resources + shared expertise = new & improved technologies

ETC Working Groups & Teams will:

- Identify areas where new commercial technology (or improvements to existing technology) would benefit the pharmaceutical industry
- Develop consensus industry requirements for the proposed technology
- Solicit interest from the community to collaborate in these areas through a public RFI/RFP process
- Consider requests from 3rd parties to collaborate on a project
- Provide subject matter expertise in support of the project
- Provide funding in support of the project

Expectations for 3rd Party Collaborators:

- Indicate interest in partnering with ETC on a project through response to RFI/RFP or making a direct request to ETC
- Provide expertise in support of the project
- Provide funding in support of the project (e.g. through shared cost model, application of ETC member costs to future discounts, etc.)
- Work with ETC project teams as collaborative partners to drive development
- Commercialize the output of a project and provide support



Get Involved

Learn more about ETC at
www.etconsortium.org



Or contact the Secretariat for more information.

ETC Secretariat
info@etconsortium.org



Backup



WHAT

is Enabling Technologies Consortium™?

WHY

should our organization participate?

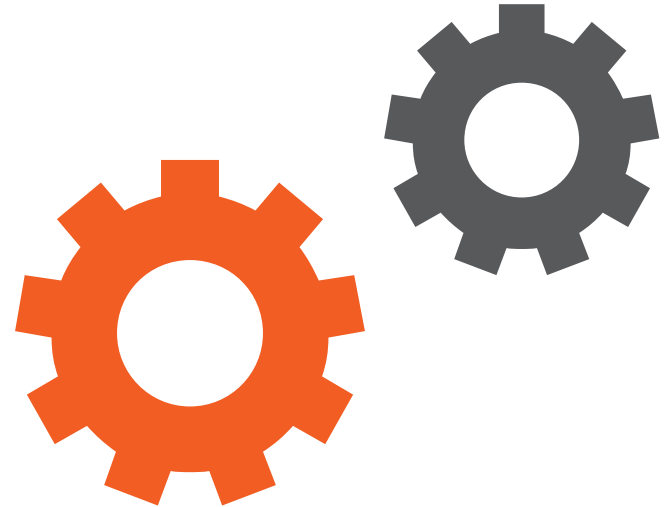
WHO

makes up the membership?



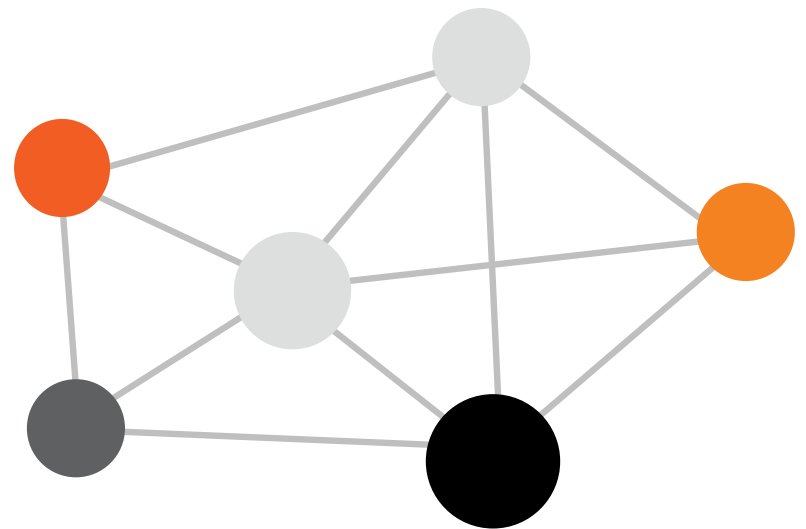
WHAT is Enabling Technologies Consortium™ (ETC)?

- ETC is a forum for member companies to discuss ideas, share information and collaborate on the development of new enabling technologies.
- ETC also gives member companies an ability to transact business with external parties (universities, vendor companies, *etc.*) to further the mission of developing enabling technologies for pharmaceutical development and manufacturing.



WHO Makes up the Membership of ETC?

AbbVie
Amgen
AstraZeneca
Biogen
Boehringer Ingelheim
Bristol-Myers Squibb
Celgene
Eli Lilly & Co.
Genentech/Roche
GlaxoSmithKline
Merck & Co. (USA)
Pfizer
Takeda



Who Can Join ETC?

The Enabling Technologies Consortium™ (ETC) is comprised of pharmaceutical and biotechnology companies collaborating on issues related to pharmaceutical chemistry, manufacturing, and control with the goal of identifying, evaluating, developing, and improving scientific tools and techniques that support the efficient development, and manufacturing of pharmaceuticals.

Membership is open to companies significantly engaged in the development of new chemical entities or new molecular entities for the prevention, diagnosis, or treatment of disease.



WHY Should Our Company Participate in ETC?

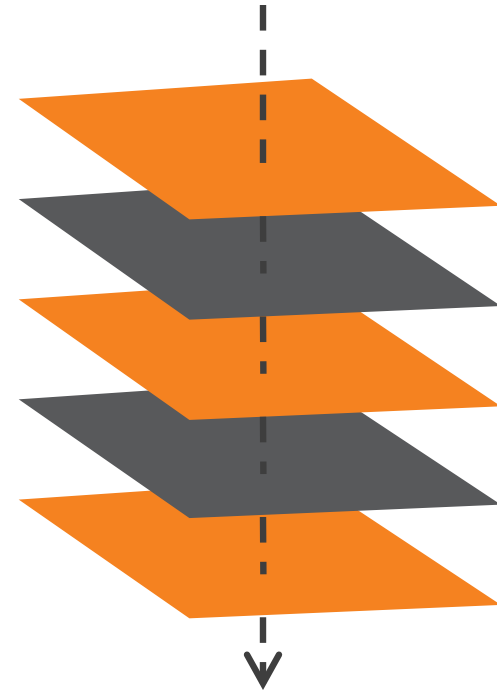
ETC provides members:

- a venue for discussion and collaboration between member companies on topics of mutual interest.
- the ability to contract work with universities or vendors under a single legal agreement between ETC and the external party.
- Streamlining, eliminating the need for parallel legal agreements between each member company and the external party that would otherwise be required for such collaborations.

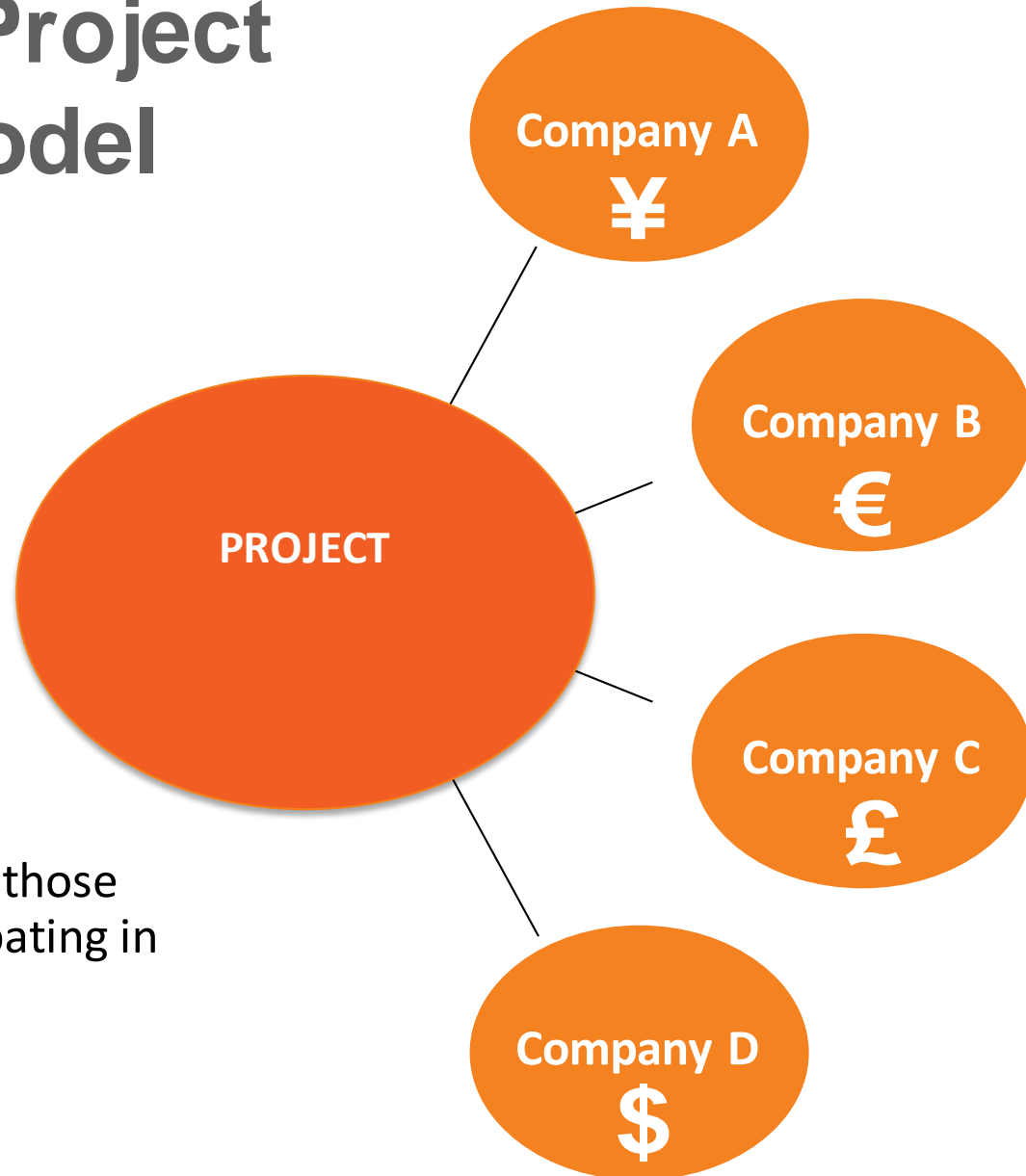


Criteria for ETC Project Funding

- ETC projects target the development of enabling technologies for pharmaceutical development and manufacturing that are deemed to be precompetitive in nature.
- Out of scope projects would include technologies deemed by the member companies to be 'competitive', or technologies outside the scope of pharmaceutical development and manufacturing.



Individual Project Funding Model



- Project costs are distributed among those companies participating in the project



Sample ETC Projects

Crystallization

Despite the plethora of experience that exists in the area of pharmaceutical crystallization considerable gaps persist that limit the efficiency of crystallization development across the industry. Given the widespread application of crystallizations and the importance of API phase and attribute control, opportunities to improve our collective approaches to crystallization process development are viewed as good investment targets.

Current reactor platforms for process development are either:

- Highly automated, high throughput; highly specialized
- Dedicated workforce
- High number of reactions, but limited data points
- Kinetic information lost
- Sophisticated, easy to use, but lower throughput (higher volumes)

Material and FTE burden to obtain data

Personal Parallel Reactor

Predicting and controlling the impact of agitated dryer process parameters on API quality attributes during scale-up and/or equipment transfer is not well understood.

The risk is the API may not meet needed quality criteria post drying for drug product performance, stability and processing.

Drying

