Group A: Hawkins/Rubin

Establish best practices for streamlining agreements

- Define team and identify accountable individuals for each party.
- Agree on a timeline with milestones at the outset (target 1-3 mo).
- Establish limits for number of live meetings each with agreed upon milestones. e.g., Three one-hr meetings then sign.
- Create “term sheets” to establish high level expectations & requirements and the associated context/reasoning.
- Start in the middle with T&C, because that’s where we’ll end up anyway!
- Establish shared technology for transparency and tracking of progress (e.g., SharePoint)

Group A: Hawkins/Rubin

Establish best practices for streamlining agreements

- A 1-3 mo timeline requires that the scope of work be known ahead of time
- There was talk of “piggy backing” off of the UIDP work leading to “Turbo Negotiator” akin to TurboTax

Group B: Tom/Orella & Group C: Welch/Thomson

Establish best practices for streamlining agreements

- Skeleton or template for universities, even if really simple
- Mine data on existing/past agreements
  - Commonalities
- Develop principles for pharma non-exclusive agreements, where vendor will sell equipment or similar.
- Define ‘typical’ agreement to assist in helping define outliers
  - Leverage CCR/UIDP to collate
- Develop clarity and education on expectations for timing

Group B: Tom/Orella

Mechanisms for Pre competitive Collaborations

- "What" is in pre-competitive space will help define how collaboration/participation will work
  - Need List of opportunities and areas for collaboration
    - utilize ongoing effort at IQ
  - Different models can be used based on the "what"
    - Vendor led, Multi-company collaboration, Joint Venture to manage, "Honest Broker" (IQ, CCR)
  - Need to incentivize and have accountability for each party in collaboration
  - Have awareness of how trust can be developed

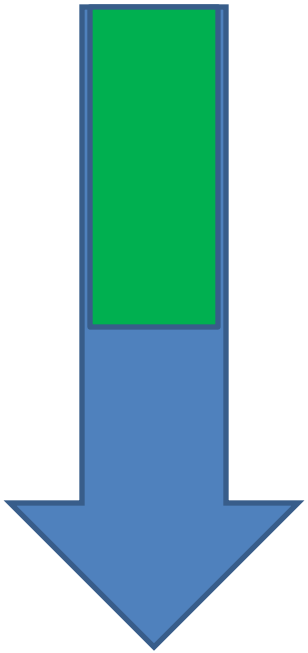
Group B: Tom/Orella

Mechanisms for Pre competitive Collaborations

- Start with smaller opportunities to show success
- Large opportunities may be on edge between precompetitive /competitive
- Need good program manager to ensure collaboration/ consortium works

Group C: Welch/Thomson

Mechanisms for Pre competitive Collaborations



- Work in parallel with independent spends/agreements but share information
- Agreement around single project with shared funding
- Agreement around multiple projects with shared funding
- Shared entity with laboratory attached

Group C: Welch/Thomson

Defining the Edges of Pre-Competitive Space

- Development of new tools- top priority
  - Chemistry
  - Equipment
  - (Software and data being handled elsewhere, e.g. allotrope)

- Share and triage our needs as a basis for further engagement across industry, academia, government and vendors

- Consider broadening scope to be more encompassing of academia, government and industry
  - '21st Century' path forward to sustainability, address bigger healthcare problem statement

- Collaboratively help create companies that provide a specific service?

Group C: Welch/Thomson

Technology Areas of Focus
Automated Parallel High Throughput Screening
Automated (parallel) lab reactors
Faster broader analytics - UPLC MS
In situ Monitoring and Characterization (Raman, FTIR and FBRM)
PAT Data Management
Computational Chemistry Algorithms
Predictive Tools for Chemical Properties
In-silico tools for Process Modeling (CFD, mixing, kinetics)
Crystallization Screening Technologies

Group C: Welch/Thomson

Defining the Edges of Pre-Competitive Space

- Share and triage our needs/areas for pre-competitive collaboration through the CCR
- Provide a list of our needs to NIST etc to facilitate interaction- OSTP
- Create a network/working group, one per pharma and a rep from academia, government and vendor community
- Do we need to broaden scope to be more encompassing of academia, government and industry?
- Ensure we work with NSF to continue dialogue on academic/government industry push for '21st century.'
- What can we leverage that already exists, e.g. IQ?
- Willingness to share our technology needs and gaps is a key enabler- are we willing to do this?

Group C: Welch/Thomson

Defining the Edges of Pre-Competitive Space

- Margaret's list
  - Lab standards
  - Lab of the future/enabling technologies
  - Analytical and purification instrumentation
  - Novel synthetic methodology and chemistry
  - GTI Predictive data and analytical methods
  - Novel excipients
  - Quality and manufacturing
  - Continuous process reactor design
  - Computational route design
  - Lab notebooks and information management
  - Automation
  - Experimental design and process modelling

Group B: Tom/Orella

Within Precompetitive Collaborations

- Lab instruments
- Measurement tools
  - Standards
- Data management, IT solutions
- Modeling – chemistry and engineering tools
  - Common standards
  - Internal standards on 'documenting' results (audit trail, etc)
- Modeling – supply chain optimization
- Unit operation equipment – primary and secondary
  - Continuous processing
  - Granulating equipment
  - Drying equipment
- Regulatory policy/strategy
- Toxicology data
  - Gene tox
  - Broader tox
- Green chemistry
  - Deal with chemistry routes, recycling, catalysts, etc

Group B: Tom/Orella

Within Precompetitive Collaborations

- Human resources
  - Training on instruments for next gen (university)
- Plant equipment in universities
- Collaborate on CMO's and CRO's
  - Share improvements and optimization that has been done
- Regulatory submission
  - Modeling results
  - Supportive data
  - First principle's for scale up
- Databases
  - tox data, solubility data
- Lab of the Future and Safety practices
  - Dow initiative
  - Academic-industry standards