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)
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
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
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
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
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
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?
### Technology Areas of Focus

<table>
<thead>
<tr>
<th>Area</th>
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<tbody>
<tr>
<td>Automated Parallel High Throughput Screening</td>
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<tr>
<td>Automated (parallel) lab reactors</td>
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<tr>
<td>Faster broader analytics - UPLC MS</td>
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<tr>
<td>In situ Monitoring and Characterization (Raman, FTIR and FBRM)</td>
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<td>PAT Data Management</td>
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<td>Computational Chemistry Algorithms</td>
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<td>Predictive Tools for Chemical Properties</td>
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<tr>
<td>In-silico tools for Process Modeling (CFD, mixing, kinetics)</td>
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<tr>
<td>Crystallization Screening Technologies</td>
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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
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
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