Experience with an ATP Study for an Automated *E. coli* / Total Coliform Method

Panel Discussion Comments

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Introduction: The ENDETEC Method

- Standard enzyme-substrate assay sensitive to glucuronidase (*E. coli*) and galactosidase (Coliform) adapted for automated reading.
- Enhanced media formulation for recovery and growth of stressed cells.
- 16-chambered automated instrument (incubate and read) for full test automation.
- Time-to-Detect: 2-18 hours depending on initial cell concentration.

Automated Micro Methods such as ENDETEC can perform “early alerting” due to continuous assay monitoring and can produce laboratory-grade results in the field – they are the future!

Objective: EPA Approval for Compliance Testing under the Total Coliform Rule (TCR)

- The TCR is the primary driver of routine microbiological testing in municipal drinking water distribution systems in the US.
- All TCR methods used for compliance (and recognized by state primacy agencies) must be EPA-approved.
- EPA provides an Alternate Test Procedure to demonstrate comparability to EPA reference methods for both *E. coli* and Total Coliforms.

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Business Benefits of EPA Approval: Way Beyond Compliance Testing

US EPA approval has become the "gold standard" – many regulators in other jurisdictions will not seriously consider a method developed in North America that is not EPA-approved.

Key Benefits

- **"Investibility":** very difficult to raise early-stage or follow-on venture capital (more on this shortly…)
- **Credibility:** EPA approval offers unparalleled "street cred" that verification programs (ETV, etc.) can't match.
- **Market Access:** EPA approval is a necessary (though not always sufficient) condition for sales to anyone but the true "early adopters".

EPA ATP Process: Our Experience Thusfar

Challenges:

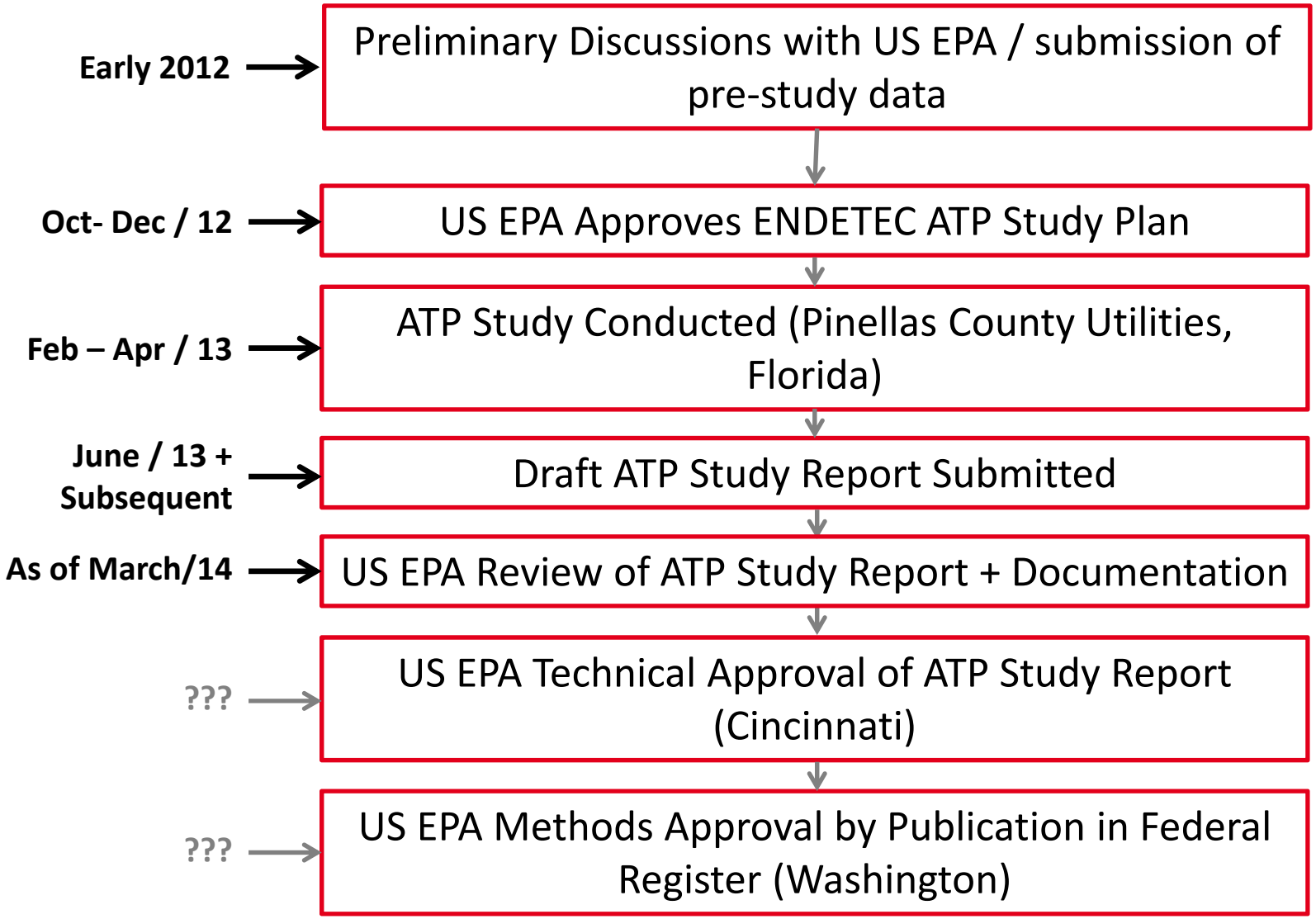
- ATP protocols need to be adapted to automated methods that have limited throughput / capacity compared to labs.
- Difference in sensitivity / performance of new methods vs. EPA reference methods leads to challenges in method performance comparison.

Upside:

- Review / comments / questions on submitted study report has been very thorough.
- Responsiveness of EPA ATP staff has been excellent.
- Genuine interest in seeing new, innovative methods go forward while “keeping the bar high”.

EPA ATP Process: Timeline

Timeline:



EPA ATP Process: Implications for Start-Ups and Venture Investors

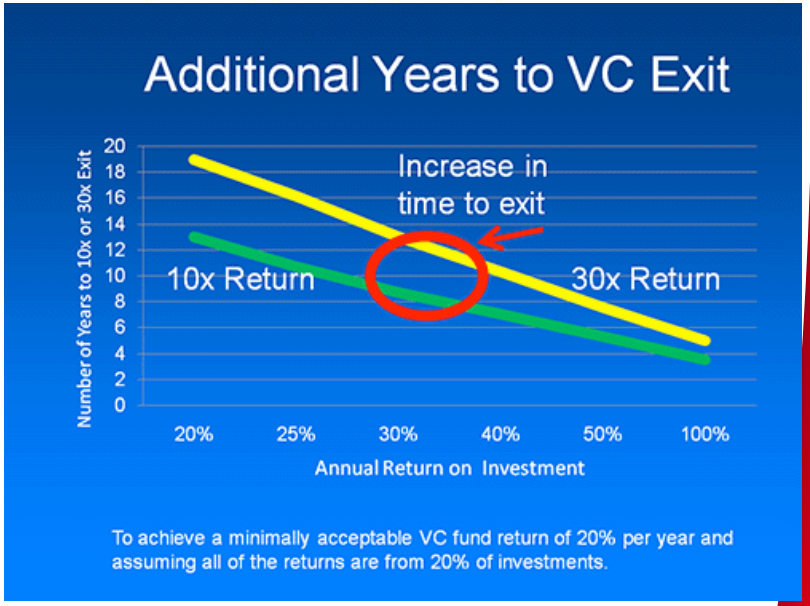
Perception:

"We don't fund regulatory risk. Period."

Well-Known Water Industry VC

Impact:

- For investors (and start-ups) – time is the enemy!
- Dramatic erosion of investor return when revenue-critical milestones are delayed.



The "Subtleties"…or What I Know Now that I Wished I Knew Then…!

Budget: less about direct costs, more about time/burn rate!

It doesn't end with EPA approval – it's just the beginning

- The "start-up revenue hockey stick" does not start its (hopefully) meteoric rise when approvals received (though it should convince early adopters to buy).
- State-level engagement (allowable methods vary by state, though many are now adopting "by reference").
- **Accreditation (example: NELAC, ISO 17025) may present even larger barriers to adoption of automated microbial methods ("thou shalt run micro in an accredited lab").**
- Some jurisdictions allow "in-line, automated" microbial methods, but grab samples from the distribution system is where the action is!

Thoughts for the Future

- **EPA**: Consider adopting (or establishing) global standards for method performance for as many analytical methods as possible.
- **EPA**: Establish standard protocols and performance-based standards (EPA Method 334 for Chlorine is a great model).
- **Cluster Organizations**: develop support resources to enable early-stage companies to mitigate regulatory risk.
- **EPA + Cluster Organizations**: Consider developing a "pre-submission" program that provides feedback and a roadmap to approval to help mitigate the perceived "black hole effect" of EPA approval actions.

Advanced sensor technologies are causing whole industries to reinvent themselves – ensure that public drinking water systems can benefit from these new technologies!

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