

The logo for the European Bioanalysis Forum (EBF) is located in the top right corner of the slide. It consists of the letters 'EBF' in a white, sans-serif font. Below the letters is a white graphic element consisting of two curved lines that sweep upwards and to the right, resembling a stylized arc or a path.

European
Bioanalysis
Forum

Feedback from the innovation breakout-session

EBF Focus Workshop “Optimizing the Pharma
CRO scientific interface in bioanalysis”,
Brussels, Belgium, 12-13 March 2015

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Background

- Workshop on Optimizing the Pharma CRO scientific interface in bioanalysis held in Brussels, Belgium, 12-13 March 2015
- Mixed attendance Pharma – CRO
- Presentations
 - Transfer of methods
 - Enhancing internal capabilities by collaboration
 - Evolution of collaboration models

Background

- Workshops: Focus on 2 areas
 - Innovation: The Scientific challenge: who will be driving innovation in the future?
 - Contracting: The changing business relationship: are contracts limiting scientific freedom?
- Breakout sessions on innovation
 - Discussions in 3 subgroups
 - Feedback was more or less the same in all subgroups
- Feedback split in two areas
 - Process innovation
 - Technological innovation

Key messages

- Innovation is key to delivering quality medicines to patients
- At risk of sounding like a pharma slogan: "The patient should remain central at all times"
- "Collaborate to innovate" - Innovation will require increase in collaborations in the next years, we will need to collaborate more and be more creative in finding innovative solutions
- Innovation is a risk that should be shared

Innovation in bioanalysis

➤ Process innovation

- New application or solution allowing better performance, efficiency, quality (e.g. solutions applying to sample management, data management)
- Optimized processes with key stakeholders
- Globally harmonized processes and templates
- Scientific validation approach

Innovation in bioanalysis

➤ Technology innovation

- Implementation of new technologies to save time and money and/or to increase quality
- Implementation of new sample preparation techniques to save time and money and/or to increase quality
- Co-development of new technologies (Pharma/CRO and technology suppliers)
- New ways of using existing technology to meet new requirements or fulfill unmet needs

What is driving / holding back innovation in BA?

➤ Driving innovation:

- Needs of patients, bioanalysis needs to provide reply to critical questions, e. g. analysis at bedside, challenging sample volume
- The drive and passion to succeed is something you need if you want to innovate
- Management stimulates innovation
- Regulatory: some innovations are driven by requests from the health authorities to answer questions
- Improvement of productivity by process innovation

What is driving / holding back innovation in BA?

➤ Holding back innovation:

- Compliance, regulators by not accepting new technology
- The work needs to be done, and innovation is the first thing to shift if deadlines need to be met, but if we can focus on and limit to doing what is really needed, we can free up time for innovation
- Innovation will take us away from our traditional way of working
 - Scientifically
 - Technologically
 - Process related

Sharing knowledge and risks

- Important to consider opportunities to share development risks through partnering (e.g. cost, profit/benefit, payment milestones). Co-investment could help innovation by sharing the risk
- We need to share knowledge and increase engagement
- How do we implement, how do we get to innovation and information sharing?
- Intellectual property can be an issue

Sharing knowledge and risks

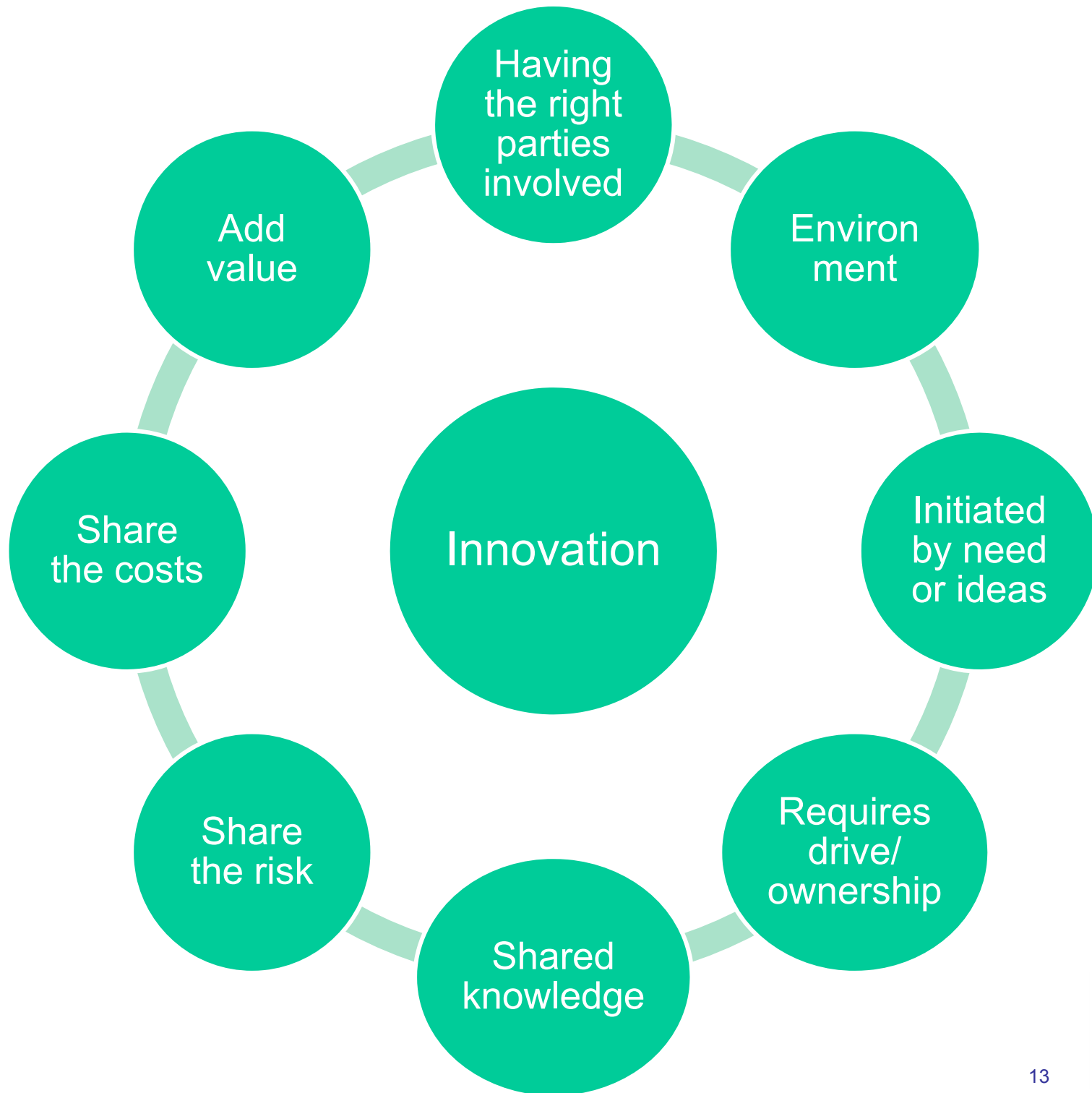
- Do we work via consortium, forum, or via individual collaborations?
- EBF and other BA forums are key to share information and new ideas
- Set up Pharma – CRO collaborations

Different parties are involved in innovation

- The “who” shouldn’t really matter. The most important is to get innovation that helps to develop drugs and cure patients
- Parties involved:
 - Pharma
 - CRO
 - Suppliers
 - Academia
 - Regulators

Areas in innovation

- Innovation in science is driven by the need for new tools
- Innovation in technologies leads to new methodologies
- New ideas for using available tools/technologies.
- Innovation in processes are driven by the need of productivity improvement (scientific validation, automation, sample handling, outsourcing strategy, document management, etc.)



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