



Several cases of EU-US
collaborations– challenges,
obstacles and possible solutions

The World has become too small

Timing is everything!

- Small Biotech company setup discovery, development and clinical collaboration with a research investigator in Belgium
- Legal paperwork takes forever but we manage to put it in place
- Clinical trial is ready to start, need IMPD for EMA submission. Why is it not ready?
- Initial clinical results are positive, recruitment is getting difficult
- Competitive drug is approved in the EU market. It's impossible to find patients. Trial is on-hold

Cultural differences: can we trust them?

- Large US medical device company acquires technology company in the EU and would like commercialize it in the US
- Tech transfer to a US CMO is key and project success depends on that collaboration
- Tech transfer is painful, EU company does not want to disclose information records, trust is broken.
- IND filing was delayed by 2+ years

A faint, light gray world map is visible in the background of the slide, centered behind the text.

We cannot ship without MTA

- A university researcher in the EU is excited about technology US biotech company is working on and would like to test it in its biological system
- This collaboration is very important and adds a lot of value to the biotech portfolio of products
- No legal contract is in place so samples cannot be shipped soon
- Legal negotiations started and could never be completed



All together on site

- Biotech company hired a CRO in the EU to run their R&D projects
- The project is moving forward OK but full transparency is lacking
- Solution: biotech company opened an office in EU
- The project was huge success!



An many more...

- Why are our batch records in French/German, etc?
- When can you send me samples? Why did it take 9M?
- Shipping: never make JFK as your port of entry
- We have to pay VAT tax? How can we set up an EU entity?



Who is your favorite biotech company?