

FIT FOR PURPOSE SCIENTIFIC VALIDATION

23 November 2018

Barcelona

EVERY STEP OF THE WAY

KEY BUSINESS CASE COMPONENTS

1

Fit for Purpose or Scientific Validation

2

Acceptance

3

Hurdles

4

Fear

5

Value

6

Future Plans

ACCEPTANCE

Some success

- **Major client uses Fit for Purpose (FoP) qualification to support preclinical**
- **Work is treated as GLP using same work flow, involving our QA**
- **In life studies are run and claim full compliance**
- **No regulatory issues over many years**
- **Client is not developing Human Pharmaceuticals!**

HURDLES

What we are tripping over.

1. **Understanding – exactly how to do SSV or FoP**
2. **Regulatory acceptance**
3. **Industry acceptance**
4. **Conservatism**

FEAR

What is holding us back.

- 1. Delays to programs – rejection of data**
- 2. Change or the unknown**
- 3. Acceptance if programs are transferred**
- 4. As a CRO standing out from the crowd**

VALUE

What do we have to gain.

- 1. Focus on doing appropriate science**
- 2. Allows the use of appropriate new technology**
- 3. Reduce the validation activities in early phases**
- 4. Implement new technology**

FUTURE PLANS

The road ahead.

- 1. Increased implementation in Pre-clinical**
- 2. Continue discussions and education with clients**
- 3. Work with industry bodies to increase knowledge and acceptance**