



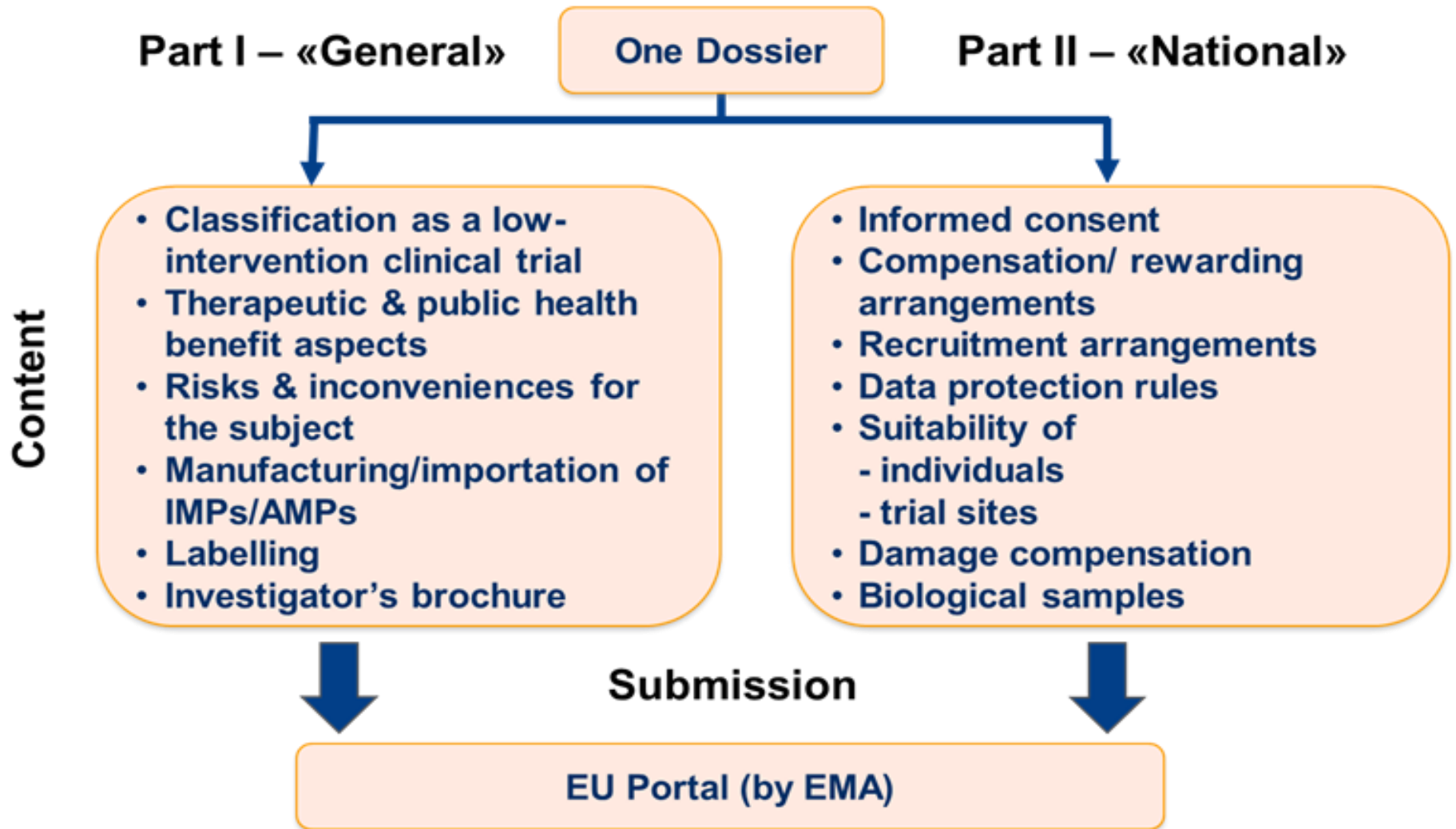
# **AHPPI Annual Meeting 2014**

**Thursday 30<sup>th</sup> October 2014**  
**Academy of Medical Sciences**

# NEW CT REGULATIONS – HOW CAN WE MAKE THE BEST OF IT?

PETER DEWLAND  
CHAIR AHPPI

# WHAT NEEDS TO BE ASSESSED?



# ASSESSMENT TIMELINES

	Validation (from submission)	Assessment (from validation to questions & reassessment of responses)	Clock Stop (Sponsor to answer questions)	Decision (from assessment)	Total
Initial Procedure (Part I & II)	10 to 25 days	45 to 64 days	12 days	5 days	60 to 106* days
Additional CMS (Part I & II)	NA	52 to 71 days	12 days	0 days	52 to 83 days
Substantial Modification (Part I & II)	6 to 21 days	38 to 57 days	12 days	5 days	49 to 95** days

May be up to 156 days (\*) or 145 days (\*\*) for clinical trials of advanced therapies or recombinant DNA derived products (extension to Assessment phase).

# HOW WILL IT WORK?

60-106 DAY WINDOW

Would be nice if quicker (especially  
Phase 1)

How do we put a “positive spin” on  
it? What do we tell our clients?

# TIMELINE

It's going to take longer than it does  
already!

How do we put a “positive spin” on  
it? What do we tell our clients?

# TIMELINE

MHRA say they will keep present  
review times

What about Ethics?

How do we put a “positive spin” on it?

What do we tell our clients?

# TIMELINE

How will central portal work?

Will it slow things down?

Validation phase

How do we put a “positive spin” on it?

What do we tell our clients?



# HOW WILL IT WORK?

Concern regarding submission and review of Substantial Amendments – timelines?

What sanctions will EC have within the proposed framework?

How will EC check the proposed facilities?

Could a form of Mutual Recognition work?

# POSITIVE SPIN

Within 60 days a GOOD application will be approved!

One with questions asked may take up to max of 3 months in as many countries as you wish

If no answer within the timeline you may proceed without any written permission!

# POSITIVE SPIN

What else can we say??

I'm looking for ideas!

From you lot!!