

# ARE ACCESS AND REGULATORY CLOSER TOGETHER?

DIA's 2018 Value, Access, and Regulatory Conference will explore progress we've made and new challenges encountered since 2017.

## 2017 Take Aways

Bringing access and regulatory strategies closer together – are we there yet?

Definition of unmet need was similar, but data requested to support the fulfilment of unmet need varies between regulators and HTA bodies.

It takes time to build trust, confidence, and common understanding across stakeholders, however, stakeholders are increasingly willing to interact together and harness existing tools. Progress is in initiating the dialogue.

Real world data can support evidence generation for treatments, where traditional randomised trials cannot be conducted, but where study designs, such as single arm trials, are used. However, these require extrapolation.

Patients are becoming more and more important partners in regulatory and reimbursement decision-making. Training them to the expert level is required to enable further development.

EMA and EUnetHTA collaboration has strengthened over the years and the joint work plan 2017-2020 has identified priority areas for further collaboration.



## 2018 Sessions and Speakers

- Multi-Stakeholder Interaction and Engagement

- EU Cooperation on HTA – Present and Future
- Multi-Stakeholder Interaction and Engagement
- Panel Discussion and Takeaways

- Acceptance of Evidence in Decision Making – Focus on RWE from Post-Launch Environment for Regulatory Decisions
- Interception, Prevention, Cure, and Repurposing: Which Evidence to Generate?

- François Houyez, Treatment Information and Access Director, Health Policy Advisor, EURORDIS, France

- EU Cooperation on HTA – Present and Future

## 2018 Actions

Paving the Way to the Future by Building Bridges



Value, Access, and Regulatory Strategy Conference  
9-10 October | London, UK

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