Key figures and dates
of the impact of Brexit for pharmaceuticals

What is the current scope of UK involvement in the pharmaceutical industry?

Pharmaceutical products are in the Top 5 most imported and exported products from the UK to the EU and vice-versa

Source: Brexit Monitor, The impact on pharma & Life Sciences, PwC

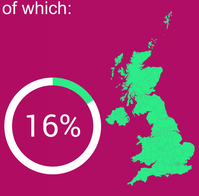
1500
Clinical trials with a UK sponsor

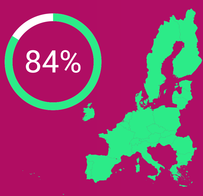
50%
Of these trials (based on the study duration) are expected to continue to run, post-Brexit

Source: BREXIT EFPIA survey, 08/11/2017

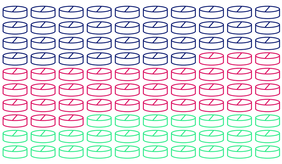
1,767
SME status holders

of which:





Source: EMA



1,165 Centrally approved products for human use

of which:

Centrally Authorised Products (CAPs) with UK based Marketing Authorization Holders

36%

Centrally Authorised Products (CAPs) with UK based Qualified Persons for Pharmacovigilance (QPPV)

27%

Source: EMA

What happens next? Key regulatory milestones for Brexit

Q1 2018

Discuss planned variations with your EMA Project Manager

Initiate Internal Change Control Procedures to effect required variation submissions (e.g. site audits, QP contracts etc.)

Q2 2018

Prepare and submit variation applications to the EMA

January 1st, 2019

Brexit Regulatory Preparedness (all your variation applications have been submitted and/or approved)

March 30th, 2019

Brexit comes into effect

VCLS
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