31.8.2016

To:
Unit B4 "Medical products – Quality, Safety and Innovation"
SANTE-B4-GL-risk-proportionate-approach@ec.europa.eu
European Commission
F101 08/058
B-1049 Brussels (Belgium)

Submission of comments on **European Commission – Guideline on Risk proportionate approaches in clinical trials** – Recommendations of the expert group on clinical trials for the implementation of Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use

Comments from:

Name of organisation or individual
EuropaBio - the European Association for Bioindustries Avenue de l'Armée 6 | B-1040 Brussels www.europabio.org Business association registered in EU Transparency Register. Identification number in the register: 1298286943-59 Contact: Riccardo Mezzasalma, Healthcare Biotechnology Manager r.mezzasalma@europabio.org

1. General comments

General comment (if any)
EuropaBio welcomes the opportunity to respond to this public consultation, which is touching on a topic of particular interest to our members. EuropaBio has had sight of the response to this consultation by the European Federation of Pharmaceutical Industries and Associations (EFPIA) and supports the comments submitted by EFPIA.