

# Regulatory sandbox for medicinal products

*Toward implementation*

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# What can we expect at the time of entry into force of the legislation?

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Sandbox provisions  
are applicable



Dedicated webpage  
on the EMA website



EC/EMA Q&A  
guidance document  
for developers



Engagement  
platform for  
discussion



# How to identify potential candidates for a regulatory sandbox?



Developers should proactively flag regulatory challenges and roadblocks related to innovative developments



Leveraging existing horizon scanning activities at EMA and within the EU Network

# How can developers contact EMA to discuss any sandbox idea/proposal?

Informal discussion between developers and regulators:

- knowledge exchange
- discuss challenges and roadblocks

## EMA Innovation Task Force

Any developer can contact [ITFsecretariat@ema.europa.eu](mailto:ITFsecretariat@ema.europa.eu)



# How are proposals evaluated?



The trigger to consider a regulatory sandbox is the identification of a **roadblock** that prevents the development of a medicine/class of medicines with full compliance to current requirements.



A regulatory sandbox is **not** a way to accelerate existing regulatory procedures nor a mechanism to lower regulatory standards and requirements.

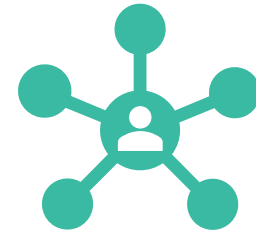
# Sandbox plan



Evidence generation plan



Tailored for each sandbox



Step-wise development and agreement: developer, EMA & network, and EC

# Next steps



Upcoming discussions at conferences and events



Contribution to IHI BRIDGE activities



Implementing act



Sandbox plan template & additional guidance for developers



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# Thank you

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