

# 臨床研究・レギュラトリーサイエンス学分野

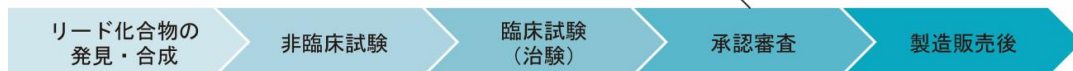
## レギュラトリーサイエンス Regulatory Science

医薬品等の有効性・安全性を科学的に評価するためのツール  
臨床評価GL作成や製販後の適正使用等も含む



### 研究例

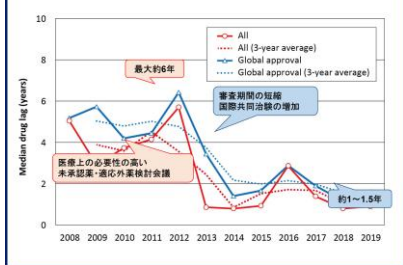
承認審査の適切性の評価  
ドラッグ・ラグの評価と分析  
レギュレーションの国際調和  
医療経済と薬価収載の考え方



医薬品医療機器等の開発の方法論  
薬事規制・医療政策の評価  
有効性・安全性の評価尺度  
計画・実施・評価・報告の適切性  
臨床評価ガイドラインの作成

製造販売承認後の安全性評価  
医薬品適正使用  
リアルワールドデータの活用方法

ドラッグ・ラグ全体の推移



本邦で承認された新薬のドラッグ・ラグ減少を初めて明らかにした。審査期間の短縮と国際共同治験の増加によって大幅に改善しているが、約1~1.5年のラグが残存している。

最大6年あったドラッグ・ラグは大幅に改善

疾患領域別のドラッグ・ラグ

Therapeutic area	全品目				海外承認あり			
	First tentative (2008-2011)	Second tentative (2012-2015)	Third tentative (2016-2019)	Overall	First tentative (2008-2011)	Second tentative (2012-2015)	Third tentative (2016-2019)	Overall
Chemical	4.3 (3.6)	3.3 (3.6)	3.3 (3.3)	3.4 (3.6)	4.7 (3.6)	3.3 (3.6)	2.2 (3.3)	3.1 (3.6)
Biological	6.0 (5.6)	3.3 (3.3)	3.3 (3.3)	3.4 (3.3)	4.3 (3.3)	3.3 (3.3)	2.2 (3.3)	3.1 (3.3)
Medical/Device	2.3 (2.1)	0.9 (0.9)	1.3 (1.4)	1.4 (1.3)	2.2 (2.1)	1.3 (1.3)	1.3 (1.3)	1.6 (1.3)
Medical	3.3 (3.3)	1.3 (1.3)	1.3 (1.3)	1.4 (1.3)	3.3 (3.3)	1.3 (1.3)	1.3 (1.3)	1.6 (1.3)
Biological	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Chemical	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Biological	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Medical/Device	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Medical	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Biological	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Chemical	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Biological	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Medical/Device	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Medical	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Biological	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Chemical	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Biological	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Medical/Device	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Medical	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Biological	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Chemical	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Biological	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Medical/Device	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Medical	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Biological	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Chemical	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Biological	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Medical/Device	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Medical	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Biological	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Chemical	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Biological	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Medical/Device	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Medical	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Biological	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Chemical	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Biological	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Medical/Device	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Medical	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Biological	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Chemical	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Biological	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Medical/Device	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Medical	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Biological	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Chemical	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Biological	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Medical/Device	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Medical	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Biological	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Chemical	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Biological	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Medical/Device	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Medical	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Biological	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Chemical	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Biological	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Medical/Device	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Medical	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Biological	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Chemical	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Biological	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Medical/Device	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Medical	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Biological	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Chemical	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Biological	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Medical/Device	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Medical	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Biological	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Chemical	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Biological	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Medical/Device	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Medical	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Biological	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Chemical	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Biological	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Medical/Device	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Medical	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Biological	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Chemical	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Biological	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Medical/Device	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Medical	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Biological	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Chemical	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Biological	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Medical/Device	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Medical	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Biological	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Chemical	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Biological	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Medical/Device	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)
Medical	2.3 (2.3)	0.9 (0.9)	1.3 (1.3)	1.4 (1.3)	2.3 (2.3)	0.9 (0.9)	1.3 (1.3	