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2004 CRO()

2019 11 5 CRO

688202

10

AAALAC

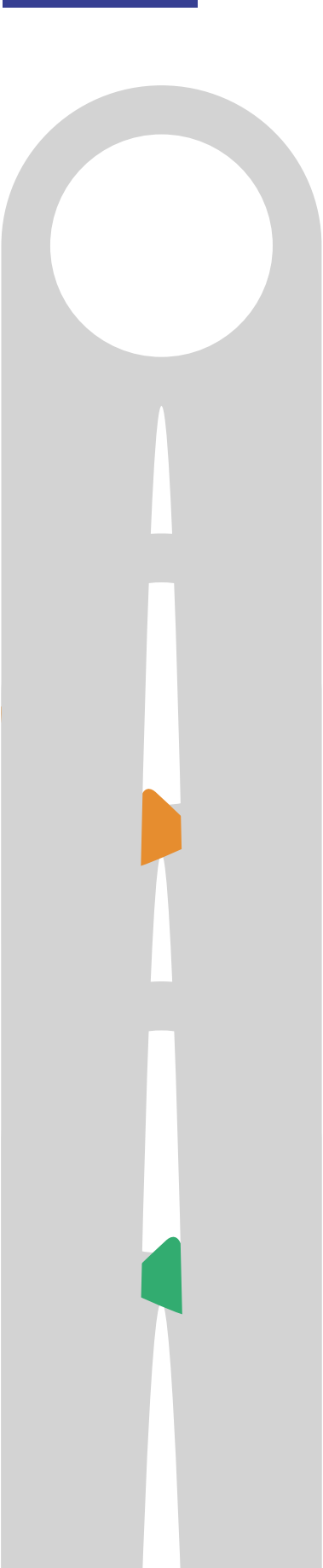
80%

NMPA GLP

30%

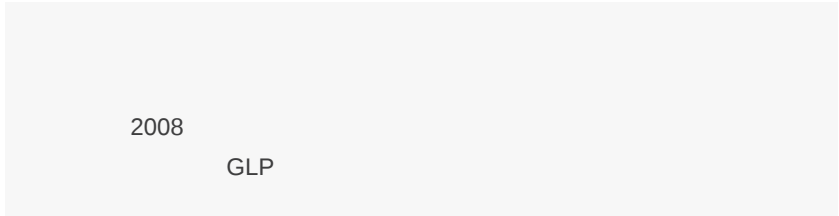
FDA GLP

U•



2004 -2008

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-
- 2



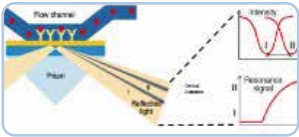
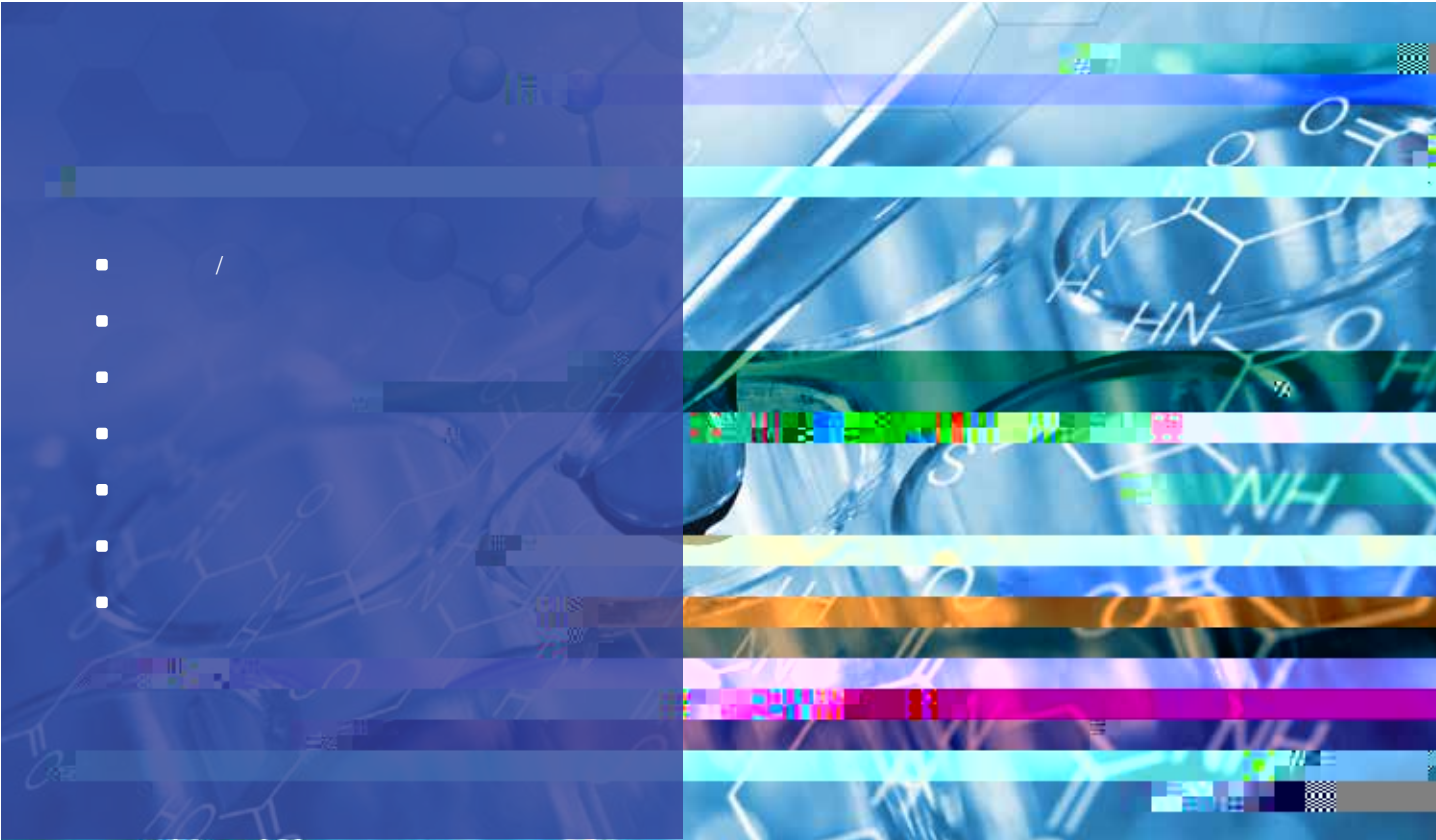
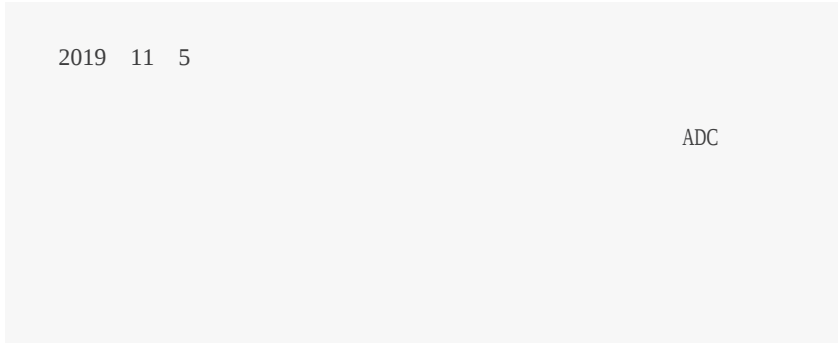
2009 -2014

- ()
-
- GLP
- AAALAC
-



2015 -

- FDA GLP
-
-



Biacore



PROTAC

RNAi CAR-T



IND

DMPK

- / / /
-
-

ADME

- P450
-
-

NMPA

US FDA

TGA

EMA

GMP

CRO

CDMO

API

API

API

DMF

(QbD)

API



01

5-10

02

BE

API

100%

API

03

2

cGMP

BE

IND

04

API

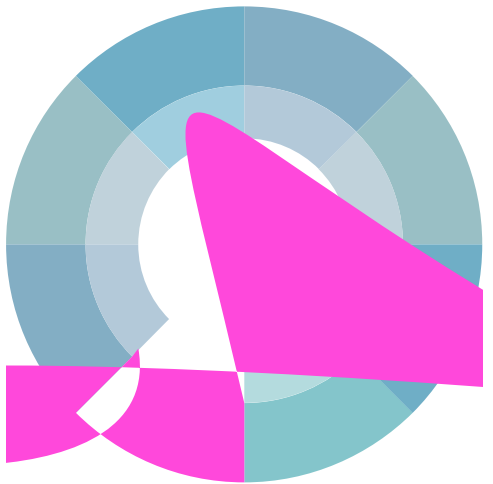
Pharmaceutical



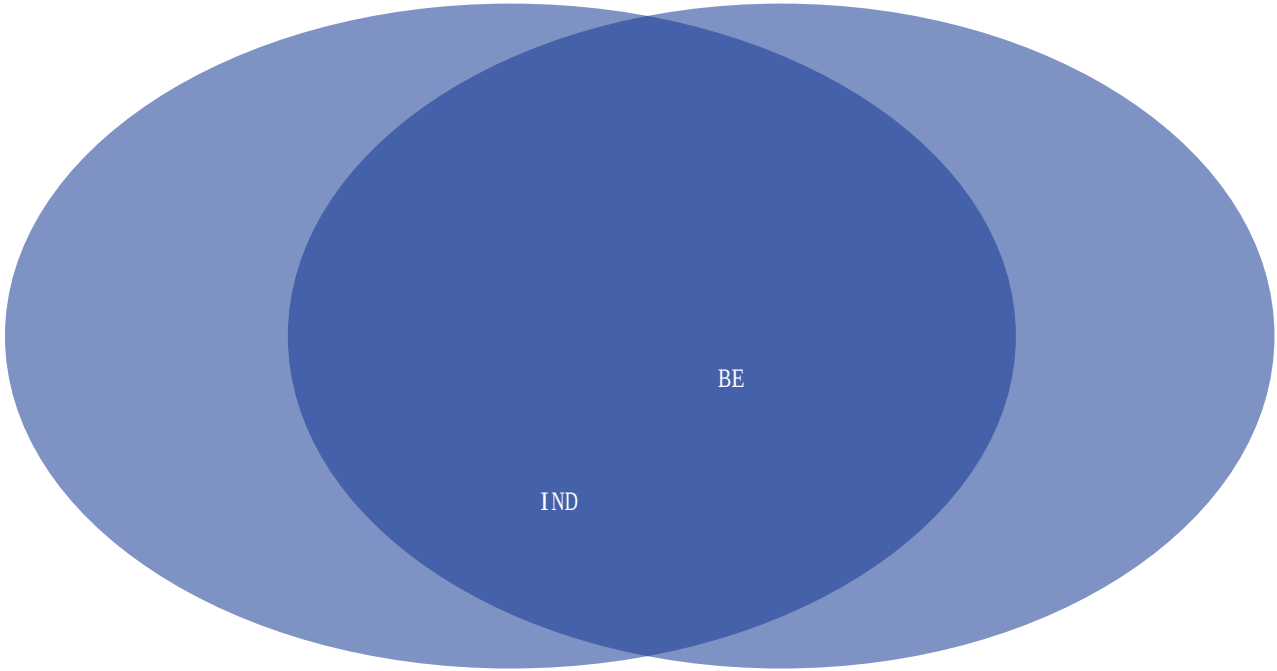
- 01
- 02
- 03
- 04
- 05

~186 ~30 ~30 ~50 ~100	PDX Models	~64 ~32 ~25 ~18 ~39
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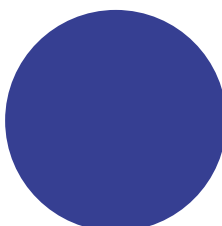
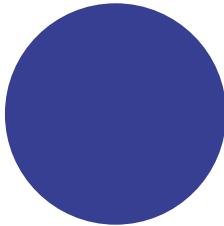
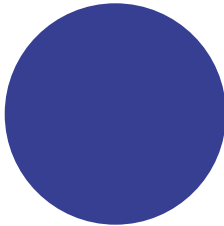
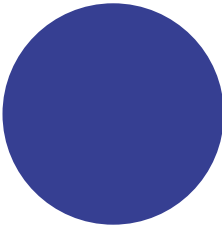
/	(含hERG测试)	- HE - IHC) - TCR)	
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IND



	:
	38 FTEs ()
	2-3 HTS
	5 1

-
- 0.9 / / , 2000
- 1Kg

- 2 , 3 , 8 , 3 assays,
- 1 , 8 with ligands.
- 20-30mg

- 65 PK
- 9
- 9 GLP

4 4

5
PK/PD

SD
SD
CYP

Caco-2

NMPA
FDA
SEND