2004 -2008

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2008
GLP

2009 -2014

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- GLP
- AAALAC
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2015 -

- FDA GLP
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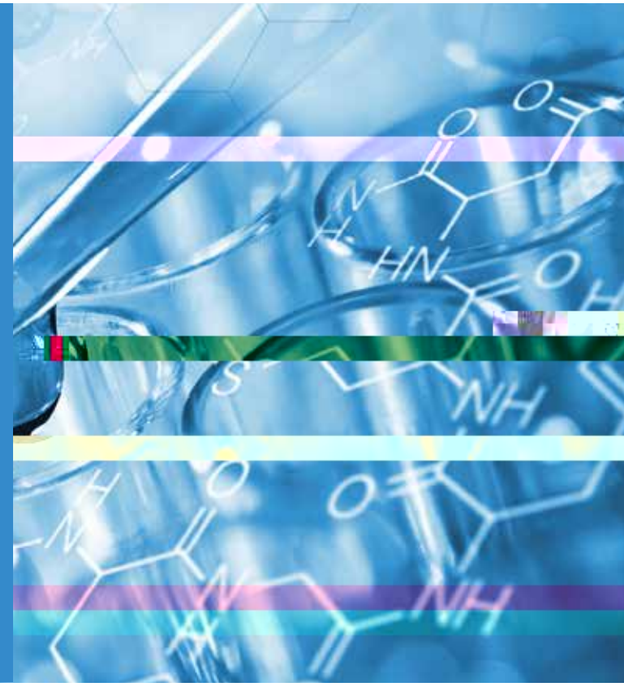

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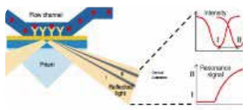

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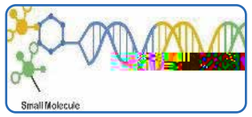

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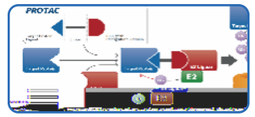

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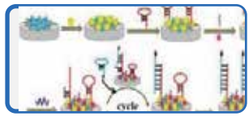

RNAi CAR-T

新药研发流程

I-III

药物发现

药学研究

临床前研究

DMPK

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-

ADME

- P450
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IND申报

NMPA

US FDA

TGA

EMA

美迪西一站式服务

SAR

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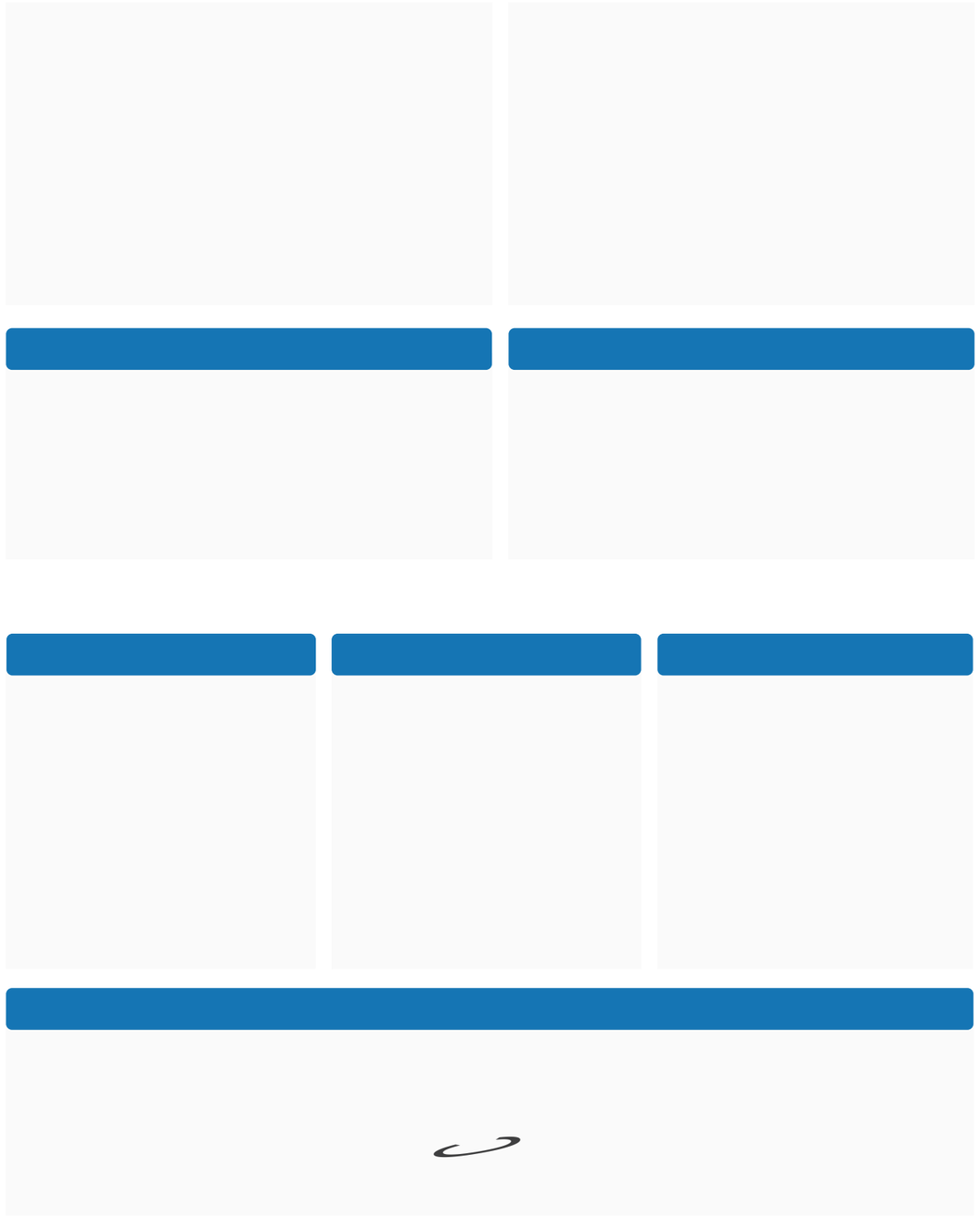

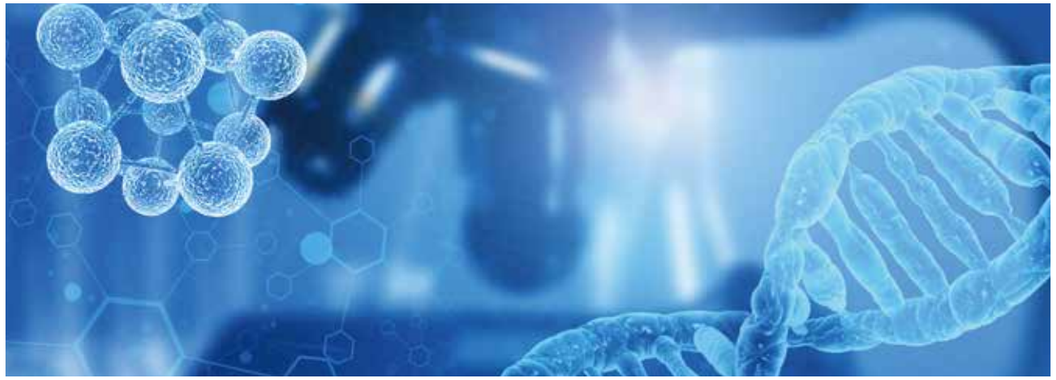

01

02

03

04

05

~140	~40
~25	~10
~30	~10
~5	~20
~5	~25

★

GLP

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- hERG

- HE
- IHC)
- TCR)

(/S9/ /)
P450 (TDI)
P450
P450 (/)
(/ /)
/
Caco-2
(P-gp/BCRP/OATs/OCTs/OATPs)
GSH

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BE/
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PK/PD

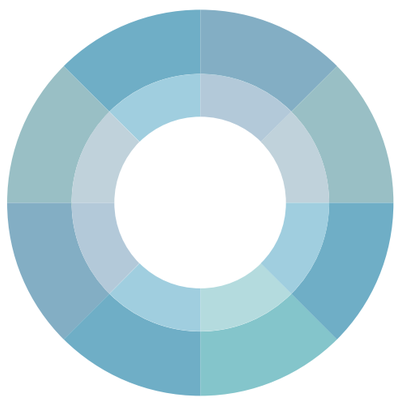
Watson LIMS
SensaTronics

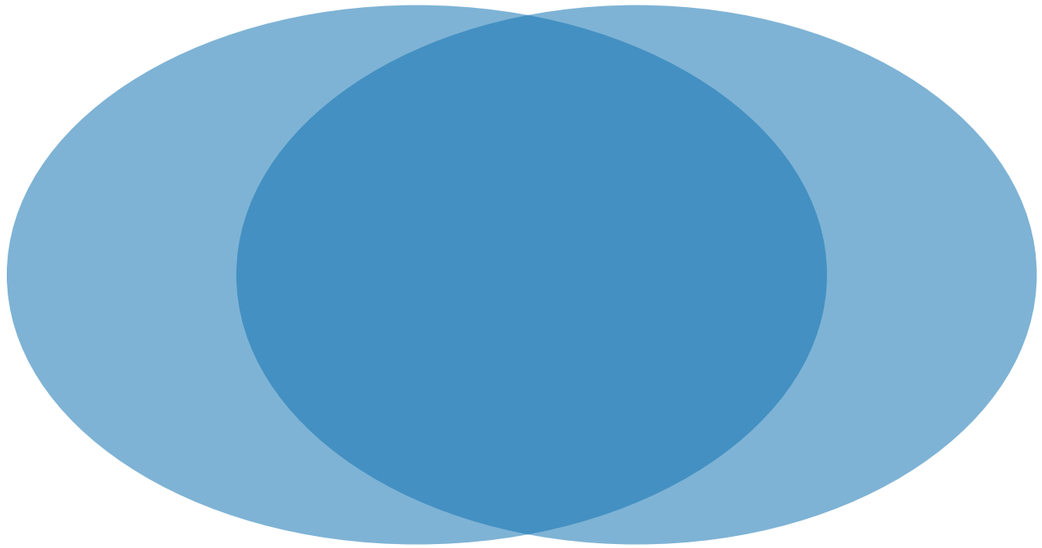
(BE) GLP DMPK/ADME

Thermo Q Exactive HF-X
Sciex Triple Quad 6500+
Sciex Triple Quad 5500
Shimadzu LCMS-8050
Sciex API 4000
Waters Acquity UHPLC
Shimadzu Nexera UHPLC
Thermo Vanquish Flex UHPLC
ICP-MS

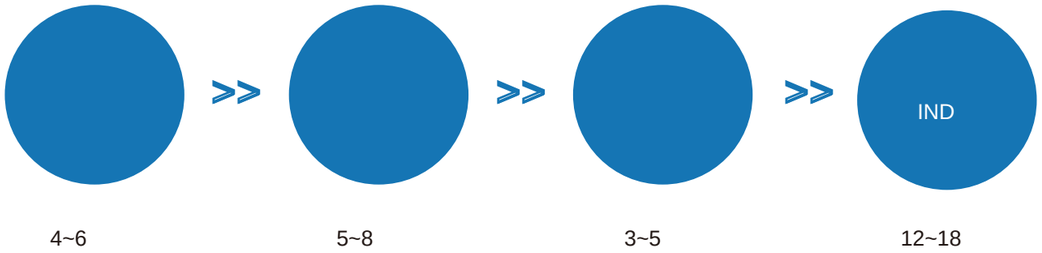
ADC
T-DM1 ADC GLP-1
PK/TK/ (Total ADA, Nab)/ /

MSD SECTOR Imager 6000
Luminex Bio-Plex 200
Gyrolab xPlore
Molecular Devices SpectraMax Plate Readers
BioTek ELx405 Plate Washer





IND



NMPA IND

US FDA IND/ANDA NMPA IND/ANDA

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- IND/ ANDA
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- NMPA FDA
- US FDA IND SEND eCTD