

iClinicalTrial™ Design & Operation Based on Intelligent Clinical Trial

Leader of Innovative Solution for Healthcare

ZHI HE

Now the health care data become the most important assets

2022

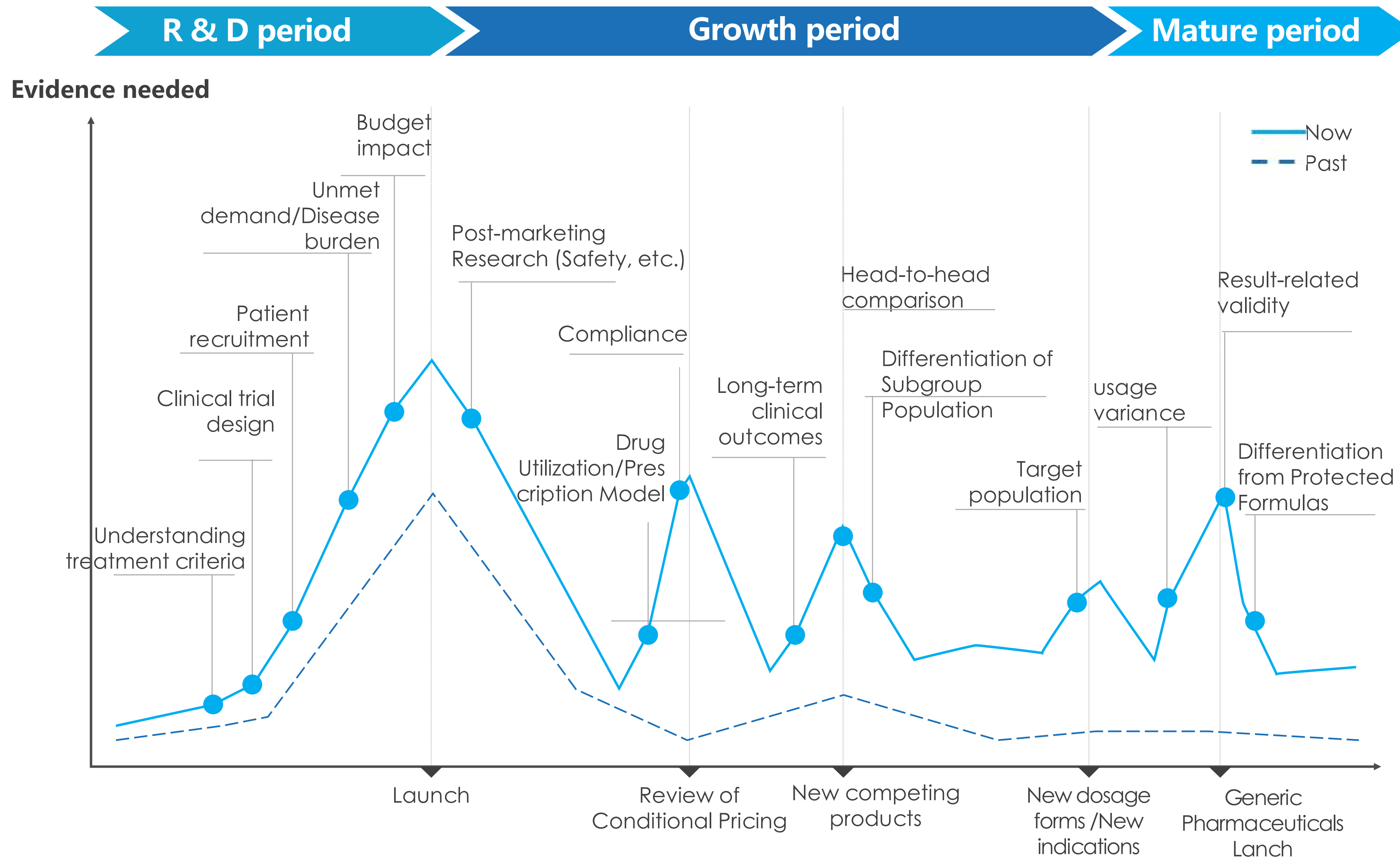
数据成为 新型医疗资本

利用人工智能与真实世界证据挖掘医疗数据价值

预计到2022年，医疗数据将成为国家重点发展的基础设施和关键企业资产，并将吸引大量资金投入。基于真实世界数据提供的信息，研究人员可提高医疗精准度，临床医生可预测患者的治疗效果。临床诊疗指南和经验将转变为计算机算法，协助临床医生和支付者制定最佳治疗方案。临床医生能够更好地了解患者的基因信息、患病阶段以及可采取的对应治疗方案。我们在传统的临床和财务数据集基础上新增了大量数据，这些数据来自物联网、患者反馈以及众多新的基因组学、转录组学、蛋白质组学、微生物组学和表观组学数据来源。医疗行业因此得以对个人和人口有一个极其详尽的了解。临床医生和医疗官员使用医疗和社会保障数据开展诊断和治疗改革，提高治疗成效和医疗生产力。制药企业与患者和医疗体系展开密切协作，利用数据开发更好的治疗方案，并提升方案启用速度，同时根据方案的医疗效果确定价格。

Source: 德勤 2022生命科学与医疗行业预测 2017.11

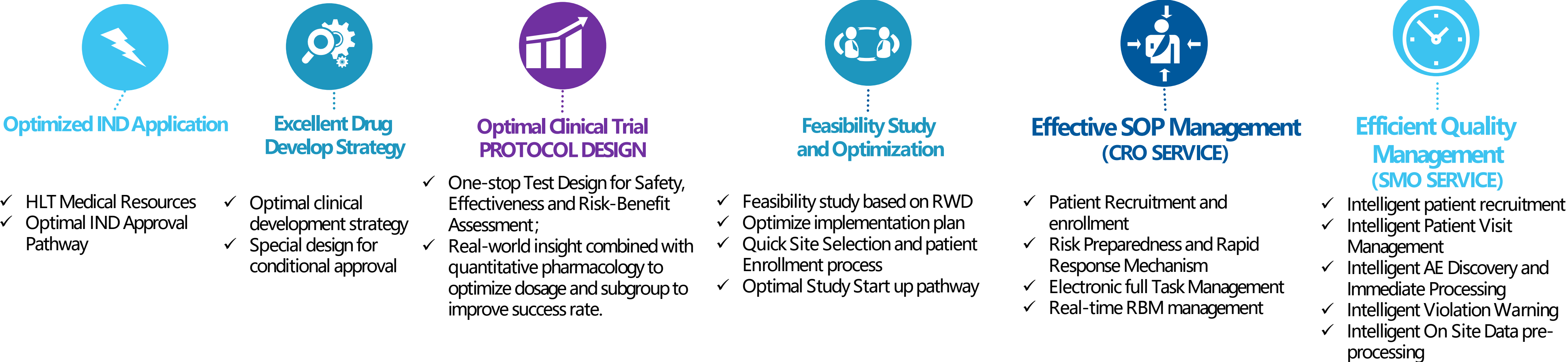
RWE is valued in full lifecycle of drugs



For innovative pharmaceutical companies, we focus on helping them accelerate the clinical development of innovative drugs

Effectively help clinical research sponsors and researchers to feasibly improve research efficiency and quality

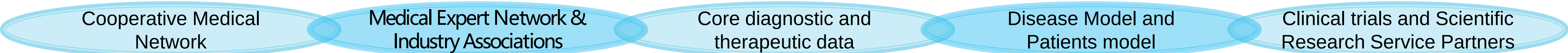
- Evidence Based Design: Unique in China -have success examples based on evidence Combining with structured RWD and prospective data for R&D
- High Quality & Efficiency: Promote 50-60% efficiency & 20-30% quality
- Empowering Manpower: Reduce 70% of CRC & CRA 's data processing cost
- Service Based on Highly Detailed SOP: Resolve questions effectively



Optimal IND Application, Clinical Development Strategy and Clinical Trial Design—Based on RWS

Precise Clinical Trial Management—Top SOP management combined with AI

DPAP SYSTEM Cooperative Medical Network+PPD CRO SOPS



RWD Help NMPA to Accept a Better DDPLAN

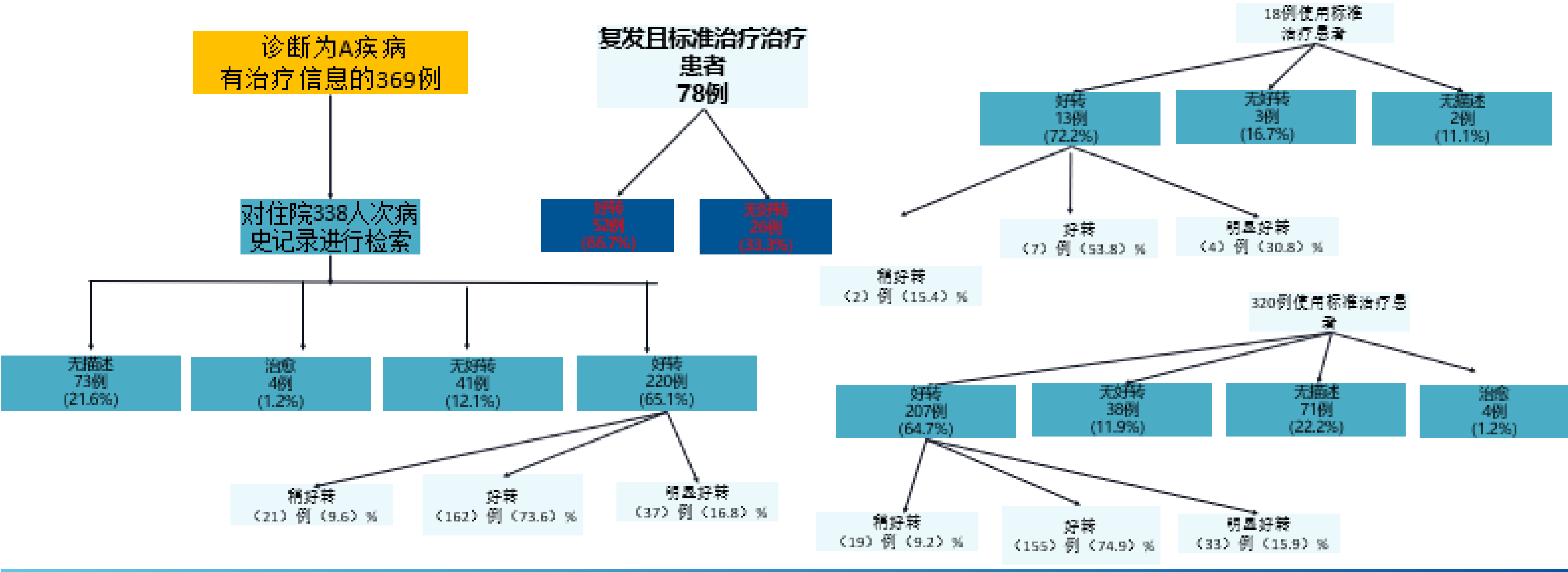


Insight

患者维度，探索患者转归情况：出院小结中提示有好转（或改善或缓解）、治愈、无明显好转或无好转或未见好转的患者比例

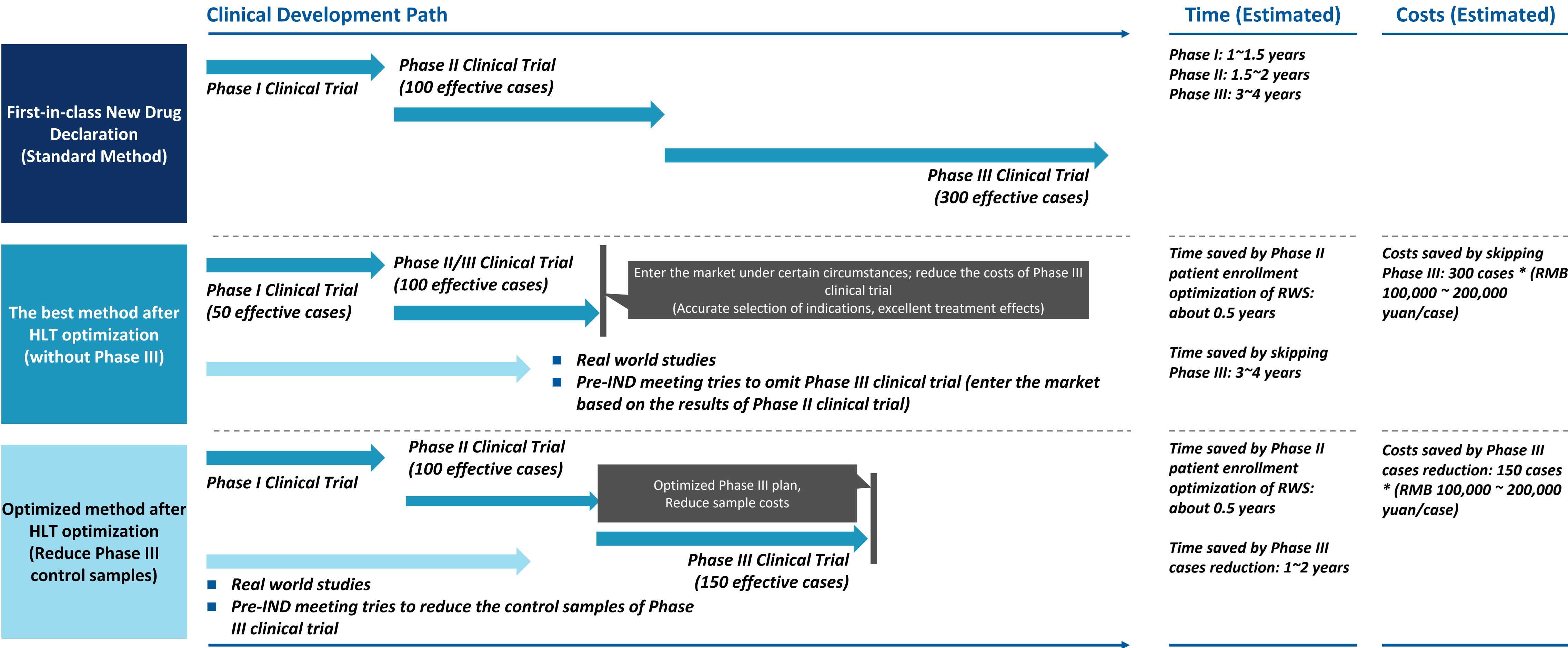
Key

患者在医院a有两次及两次以上的住院史，且接受标准治疗的疗效评价



RWD Help NMPA to Accept a Better DDPLAN

A new bio-new drug cooperation case (FOR REFERENCE ONLY)



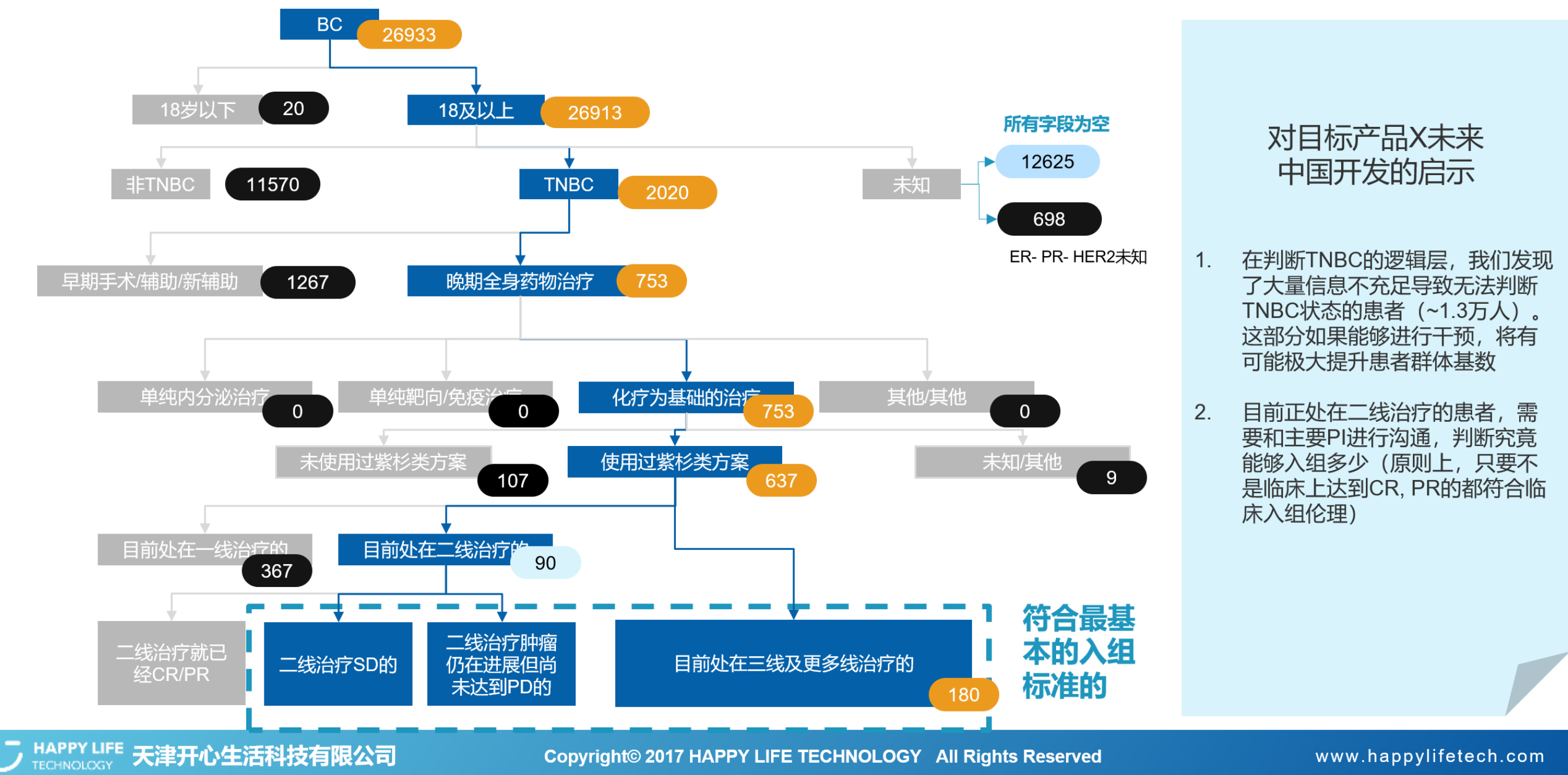
Note:
The assessment on this page is an estimation based on the above test sample hypothesis and the general test completion time. The specific cost savings can only be evaluated in detail after the PRE-IND meeting according to the optimized clinical pathway approved by CDE.

Case: Optimize patient enrollment plans and accelerate enrollment based on Real-World Data

Prediction of patients enrollment
for Tumor Drug XXX Phase III clinical trial

代表医院2016-2018治疗的患者中符合入组条件的共~270位

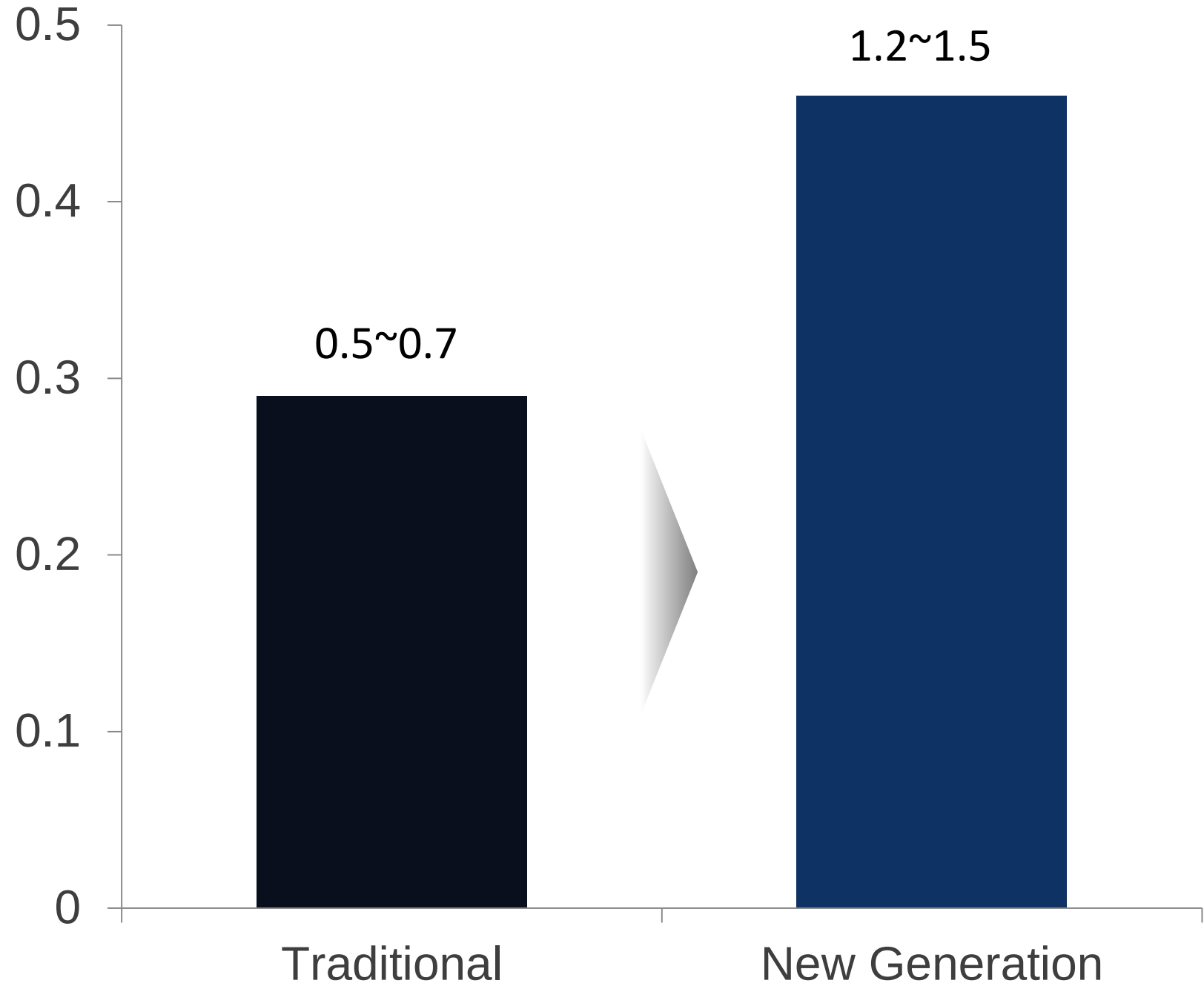
2016-01-01至今, XX肿瘤医院符合全部入组条件的TNBC患者数量



Improve patient enrollment speed by

60%

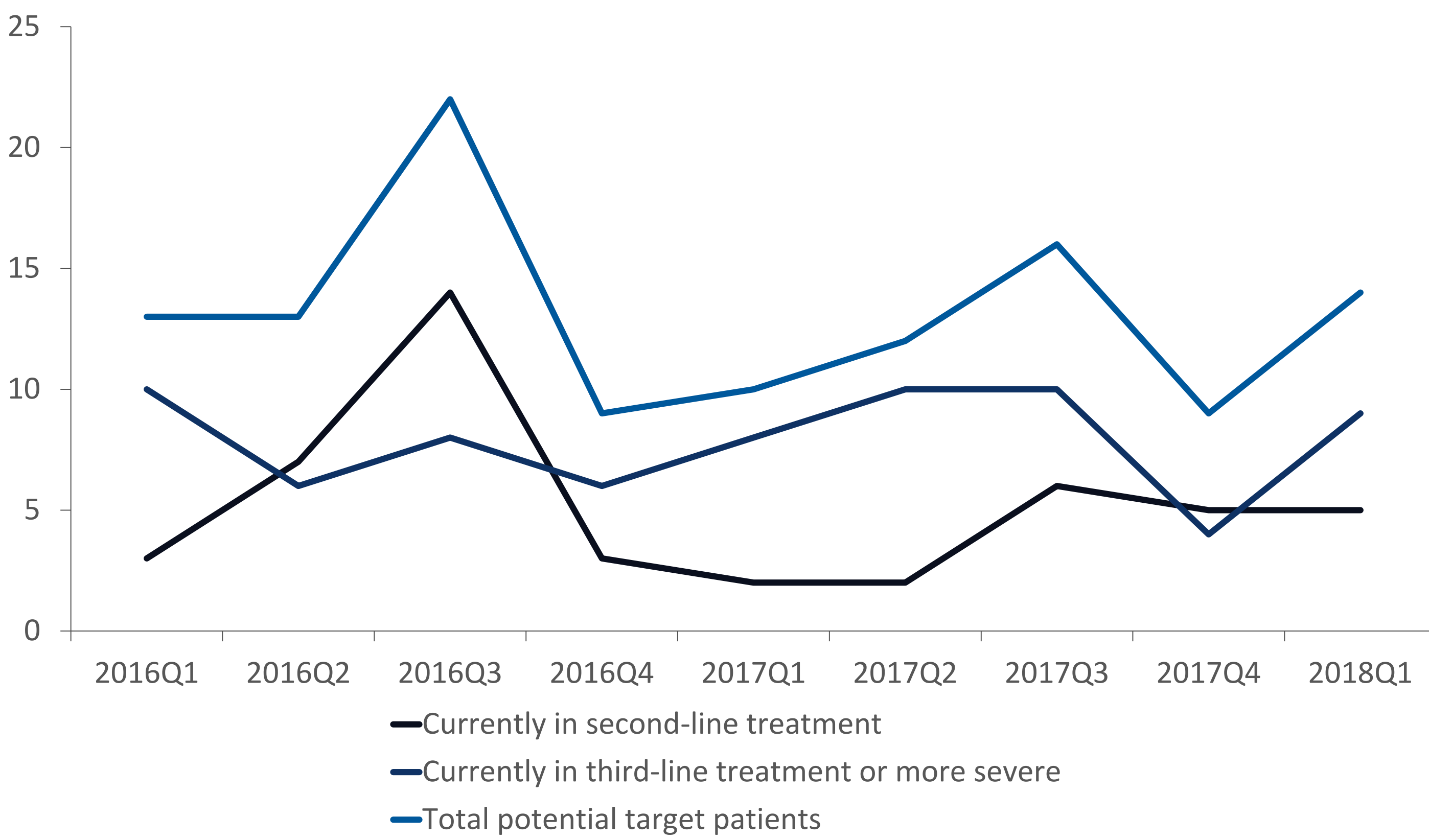
Predicted number of people enrolled in the center per month



Note: The above examples are for illustrative purposes only and the results may vary.

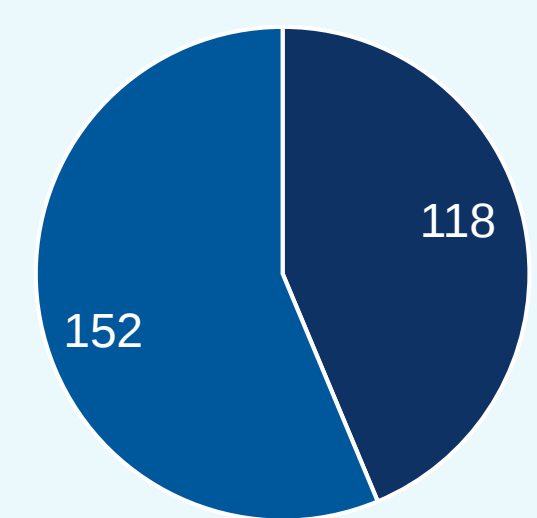
Case: Optimize patient enrollment plans and accelerate enrollment based on Real-World Data

Ever since January 1, 2016, the number of triple negative breast cancer patients from Second-line to Third-line therapy who meet the enrolment conditions



Enrollment Strategy

- 1. First of all, when the TNBC patients who had received third-line treatment before 2016 are not included, there are 71 patients who have entered the third-line treatment from second-line treatment during 2016-2018. Besides, there are 47 patients still in the second-line treatment who have the chance to be enrolled
- 2. Secondly, since there are patients who had entered the third-line treatment before 2016, there are still 152 people who are likely be still alive and are still being treated, some of whom can be recalled through a return visit

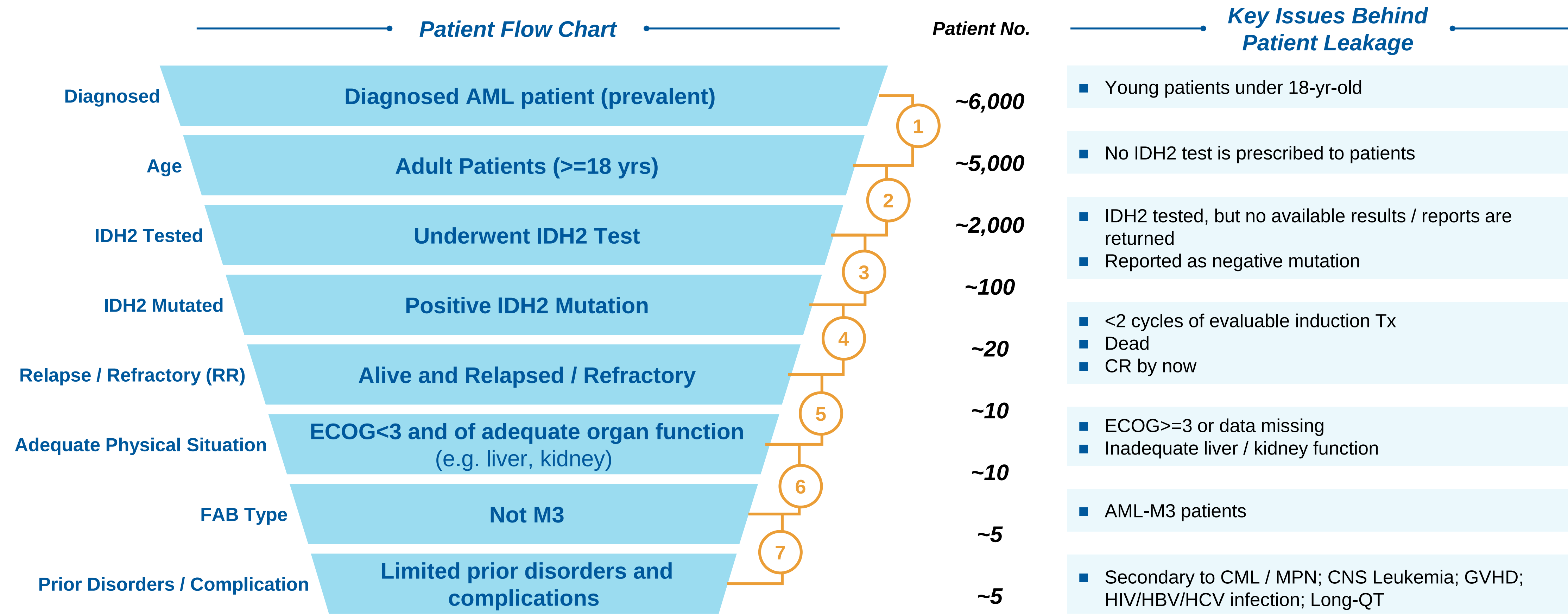


- Start third-line treatment after 2016
- 2010-2015 (12/31) Already in the third-line treatment (need to view the cases one by one)

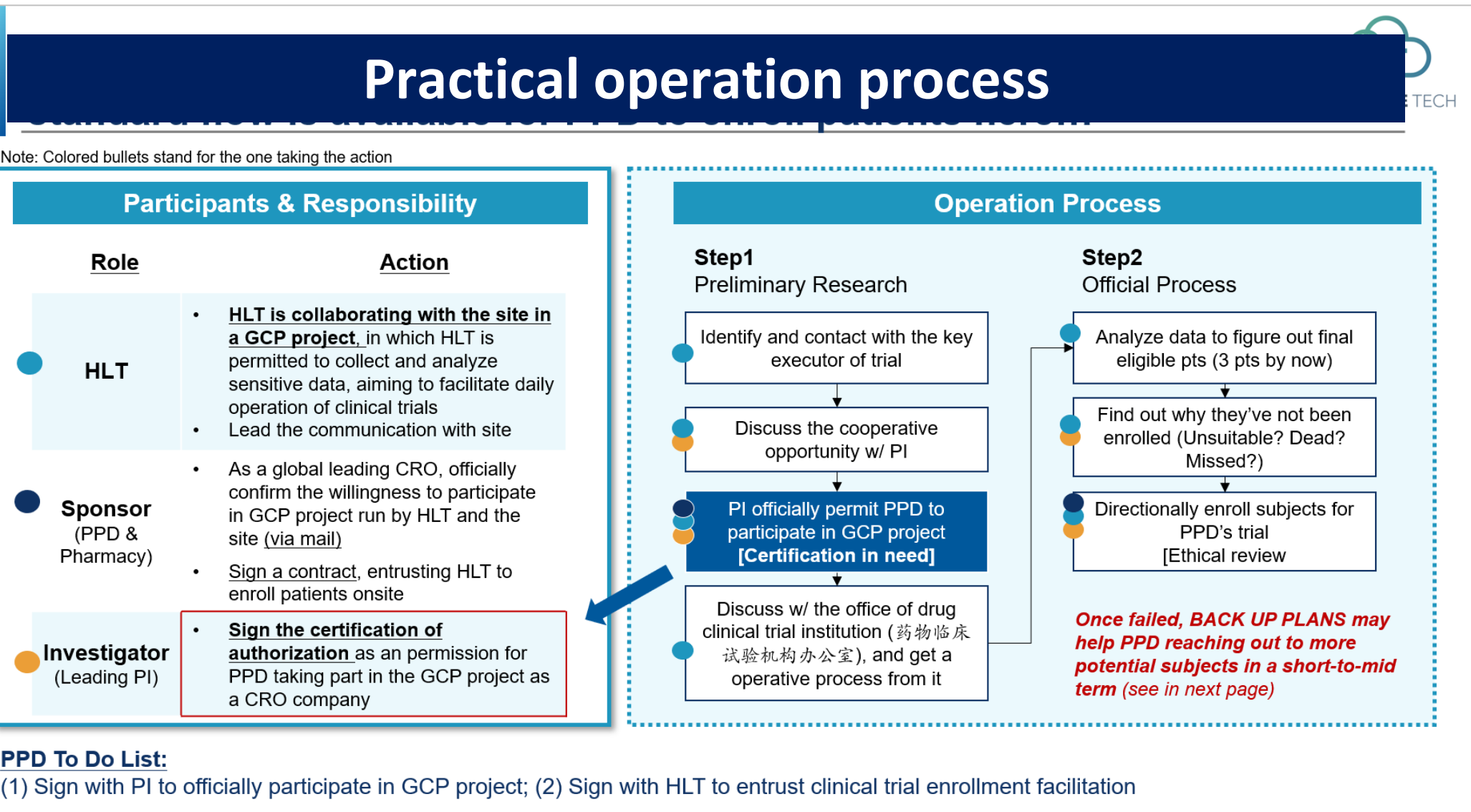
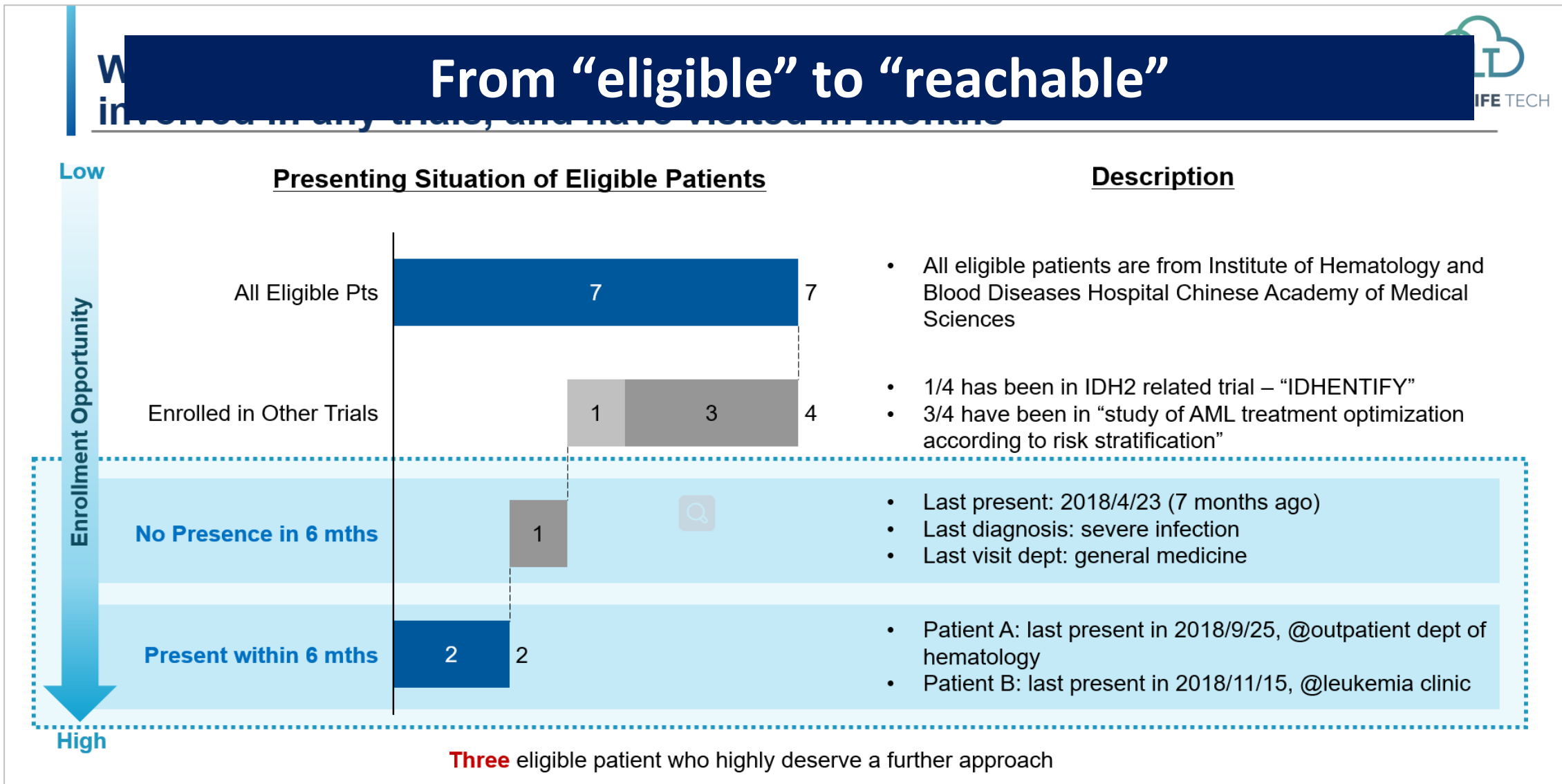
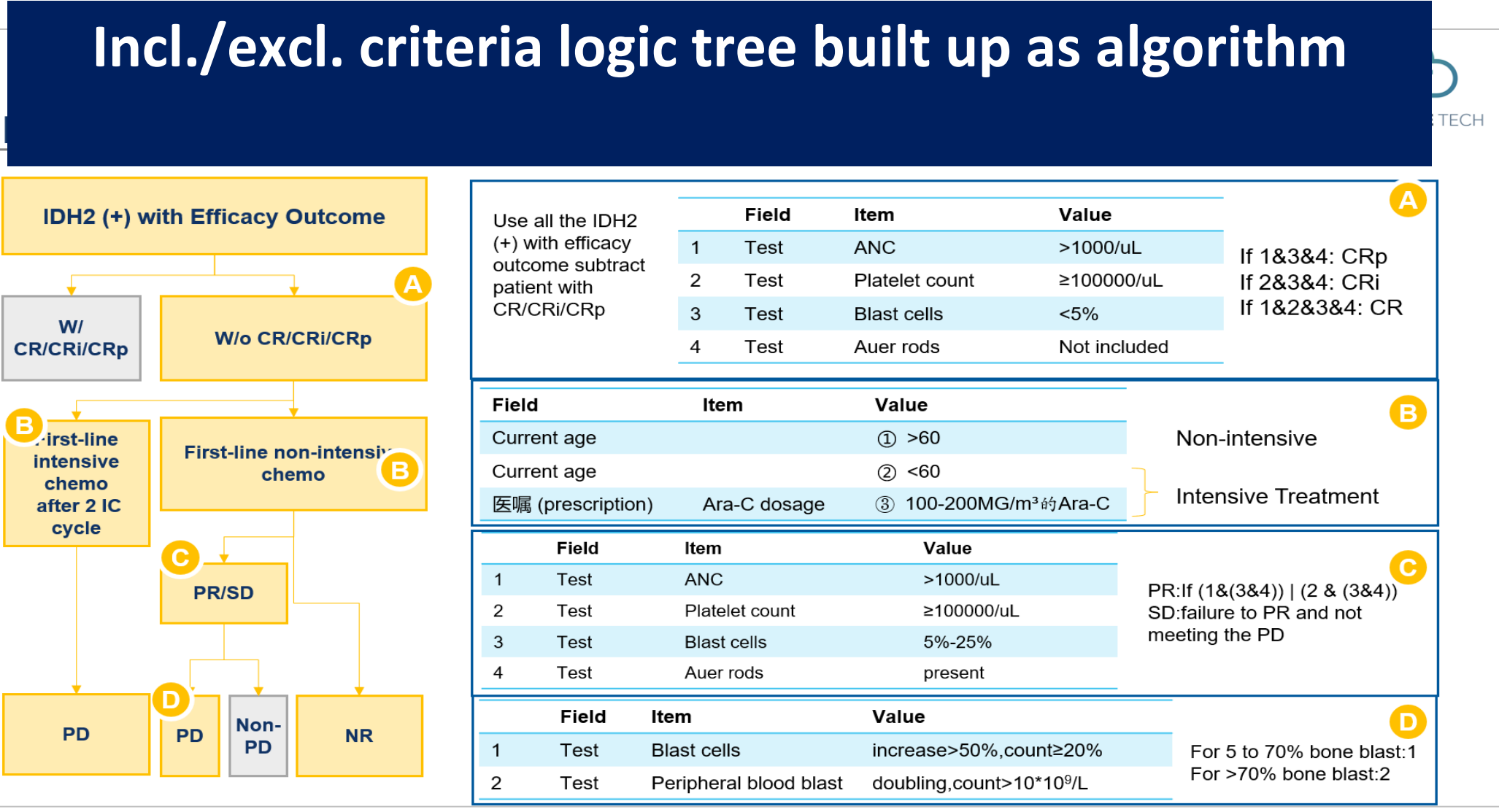
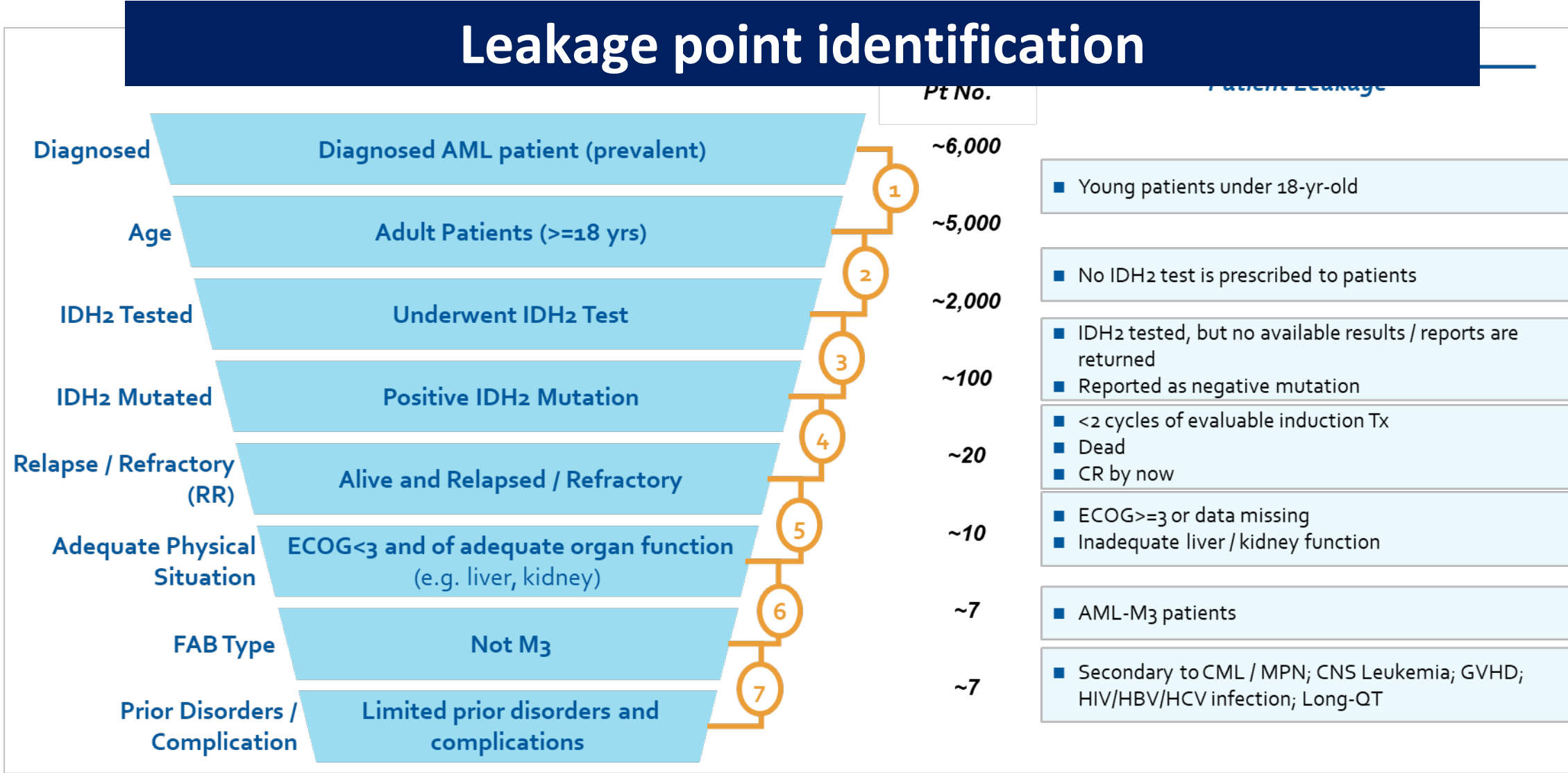
Case: Optimize patient enrollment plans and accelerate enrollment based on Real-World Data



Illustrative

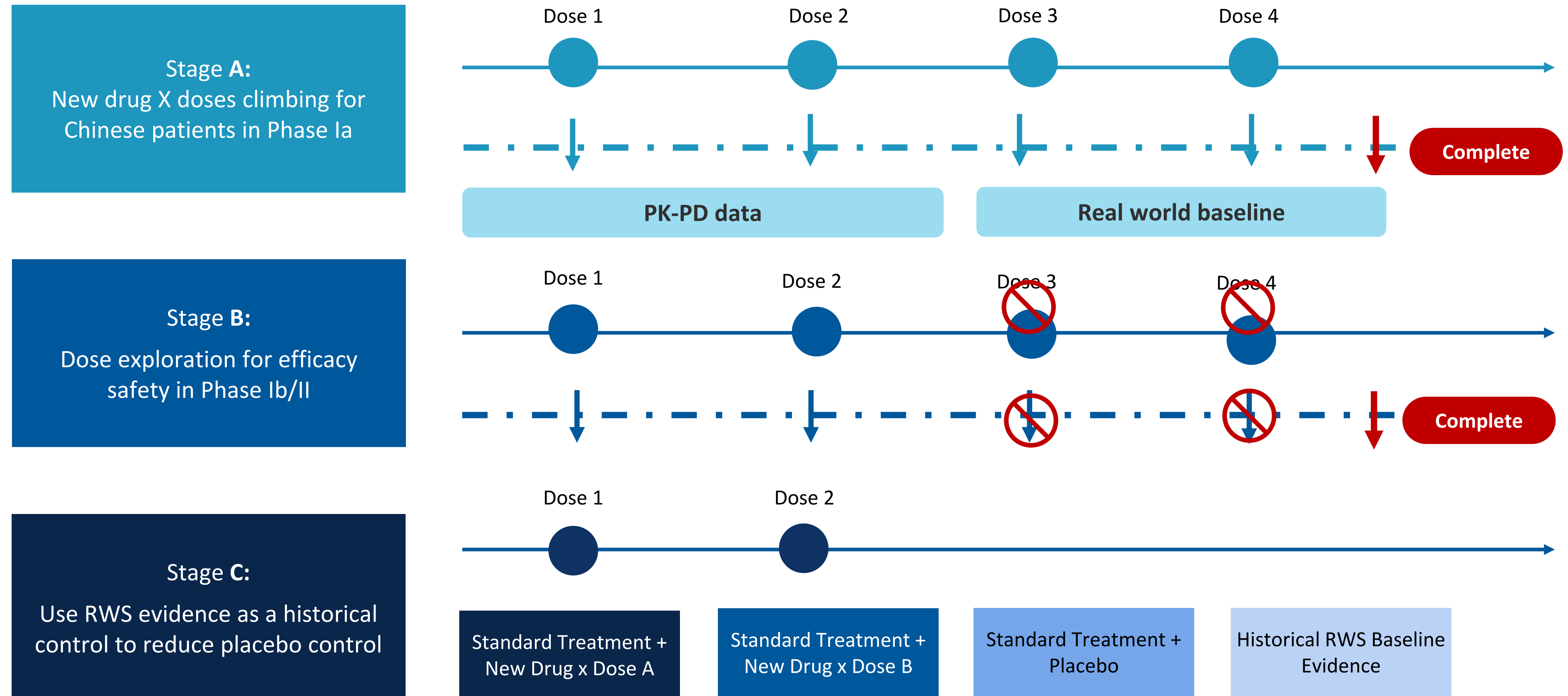


Case: Optimize patient enrollment plans and accelerate enrollment based on Real-World Data



D

Case: Through Real-World Data analysis, and combined with PK-PD model, in the dynamic clinical trial design, more accurate positioning of the population and dose groups will raise test success rate



HLT--Faster, Cheaper, Better



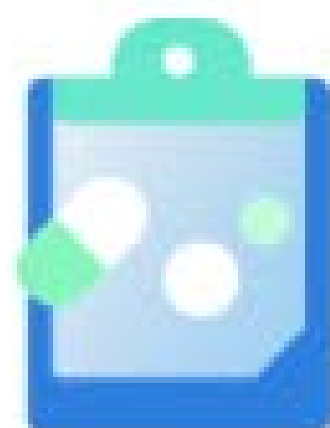
Network hospital

Covering nearly 100 top hospital networks in 22 provinces



Massive Expert Resources

It covers more than 100,000 clinicians. More than 200 academicians and chairman experts



Medical Data Integration and Processing

Leading Artificial Intelligence Technology Processing Massive Core Medical Data

HLT Helps Pharmaceutical Enterprises R & D

➤ Clinical Research :

- Pre-clinical trial: evaluation of clinical trials design, pre-experiment, selection of center and PI, recruitment of intelligent patients
- In clinical trials: project management, clinical trials data collection, report management, adverse event management

1. Explore a previously non-existent clinical pathway

- Reform with CFDA
- Combining strong registration strategy-making capabilities
- Evidence Based on China's Real World
- Explore a new clinical approach and approval method (adaptive approval)

2. Improving the Efficiency and Success of Clinical Trials

- Upgraded version feasibility study and protocol optimization based on real world and industry experience
- Process management based on the real world and eGCP to reduce patient dropout rate and data error rate

HLT--Faster, Cheaper, Better

HLT iClinicalTrial

+

EDC

+

**CRO/SMO
Cooperation**

Integrated management	PM	↓ 5% Cost
Patient recruitment	CRO	↑ Faster recruitment ↓ Reducing clinical procedures
EDC Automatic input	CRC	↓ 35% Cost
Remote SDV Management	CRA	↓ 5% Travel, site visit Cost
	DM	↓ 15% Workload

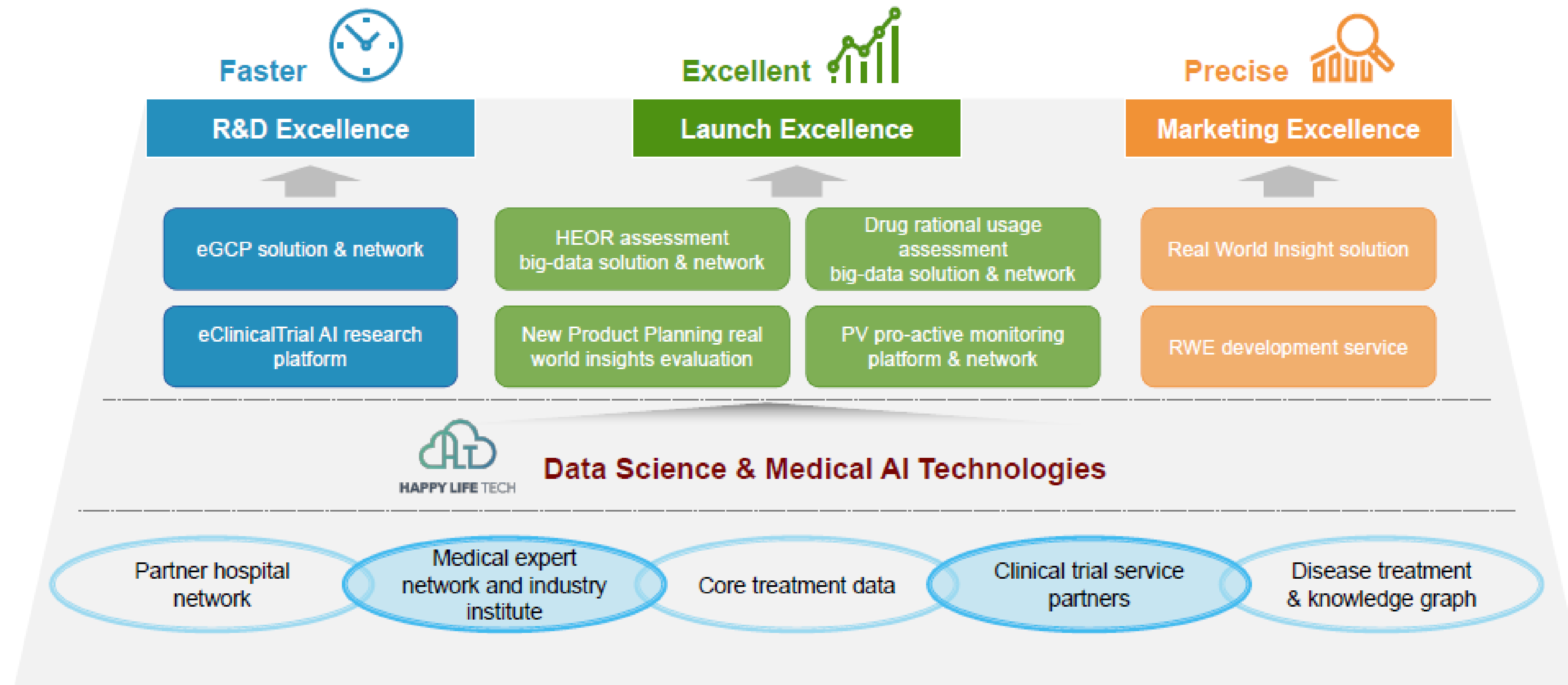
HLT provides dedicated overall solution for medicine sector



HLT PHARMA

HLT provides dedicated overall solution for medicine sector

Big data science and medical AI technology driven service solution for full life cycle of products.



HLT Pharma: Leader of Innovative Solution for Healthcare



HLT Pharma is a company of HLT Group, We are committed to apply leading big data science and artificial intelligence technology to the management of drug life cycle services and pre- and post-patient treatment, It will help enterprises to develop new drugs and rational use of drugs, accelerate the listing of high-quality drugs, improve the safety and effectiveness of drugs in the course of diagnosis and treatment, supervise the safety of drugs after listing, and benefit patients, medical institutions, pharmaceutical companies and social health, is a Leader of Innovative Solution for Healthcare.



Thanks!

