



中国结核病临床试验合作中心
China Tuberculosis Clinical Trial Consortium (CTCTC)

China Clinical Research Network Development

Introduction of China Tuberculosis Clinical Trial Consortium (CTCTC)

4th Annual RePORT International Meeting
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CTCTC Begins.....

➤ Background:

- Rapid development on TB drug and regimen globally.
 - High quality clinical trial sites in high burden countries are urgently needed
- CTCTC established in Sep, 2013 with first 12 CFDA certificated GCP sites.
- The leadership and management of the Consortium is located at **Beijing Chest Hospital**
- FHI 360 was selected to work with NIAID/DAIDS to support CTCTC network.



CTCTC Vision: Leading China's effort in conducting high standard clinical research on TB treatment, diagnostics and vaccine, to support evidence based response to TB epidemic.

Beijing Chest Hospital, Capital Medical University
Beijing TB & Thoracic Tumor Research Institute
Clinical Center on Tuberculosis, China CDC (CCTB)
WHO Collaborating Centre for Research and Training on TB



中国结核病临床试验合作中心
China Tuberculosis Clinical Trial Consortium (CTCTC)

- Grade IIIA hospital with 612 bed, 200 for TB
- TB and lung cancer
- 12000 inpatients/year
- 28000 outpatients/year

Clinical
Service

Training &
Education

- National training workshop/year
- National web-based TB consultation & training Platform
- WHO CC for TB Research and Training

- 8 research departments
- CFDA certificated GCP sites for TB & lung cancer
- Leading national TB clinical trial network (CTCTC)
- Leading China TB hospital Consortium (101 hospitals)

Research

Disease
Control &
Prevention

- National clinical center supporting NTP



CTCTC Development Phases

Established

Sep 2013

12 sites

- Regulation
- Mechanism
- Structure

Developed

16 sites

- Site assessment
- Extensive training
- CTCTC SOP development

Expansion

20 sites

- CTCTC research groups
- Strengthened assessment, training and cooperation
- Academic communication
- Initiate clinical researches

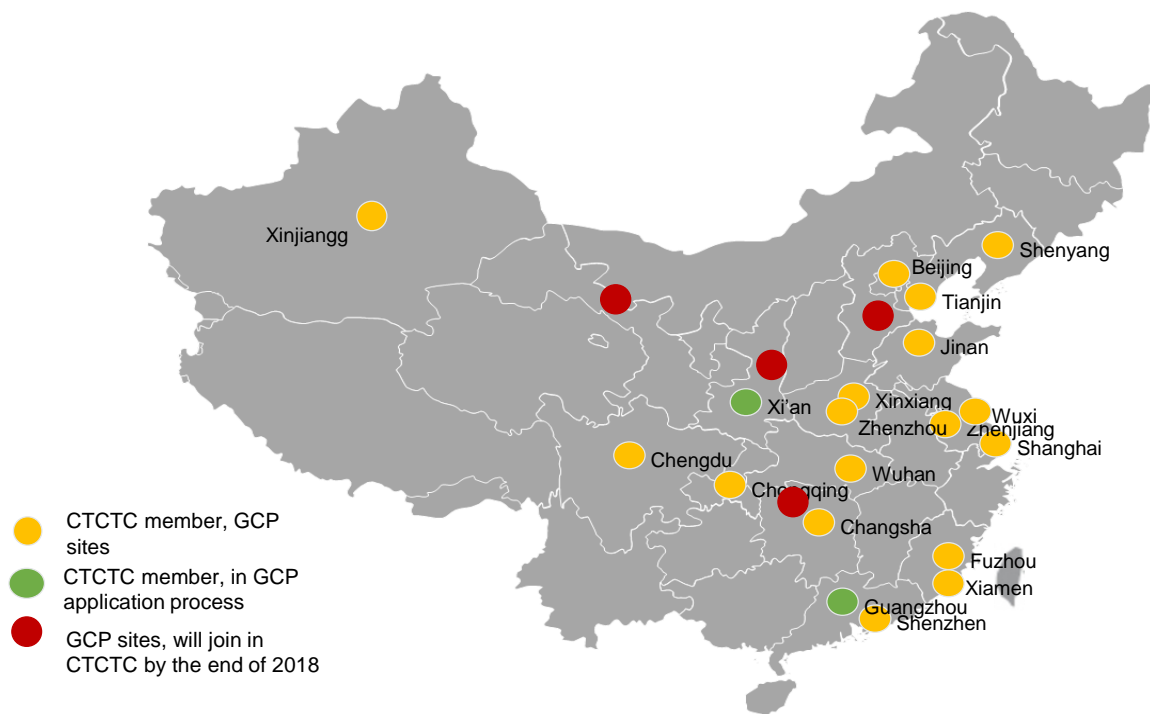
Current and the future

24 sites (by the end of 2018)

- Research grants;
- Focus on quality;
- Promote international cooperation;
- Expand influence of CTCTC.



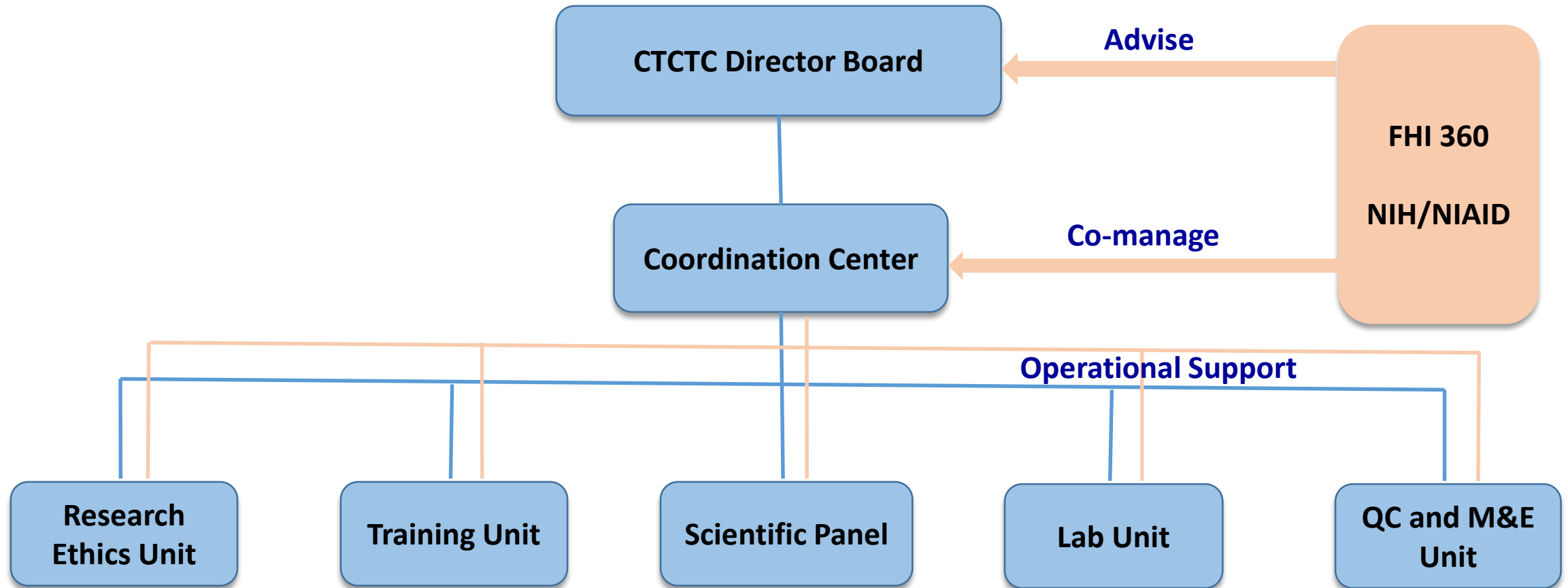
CTCTC member hospitals



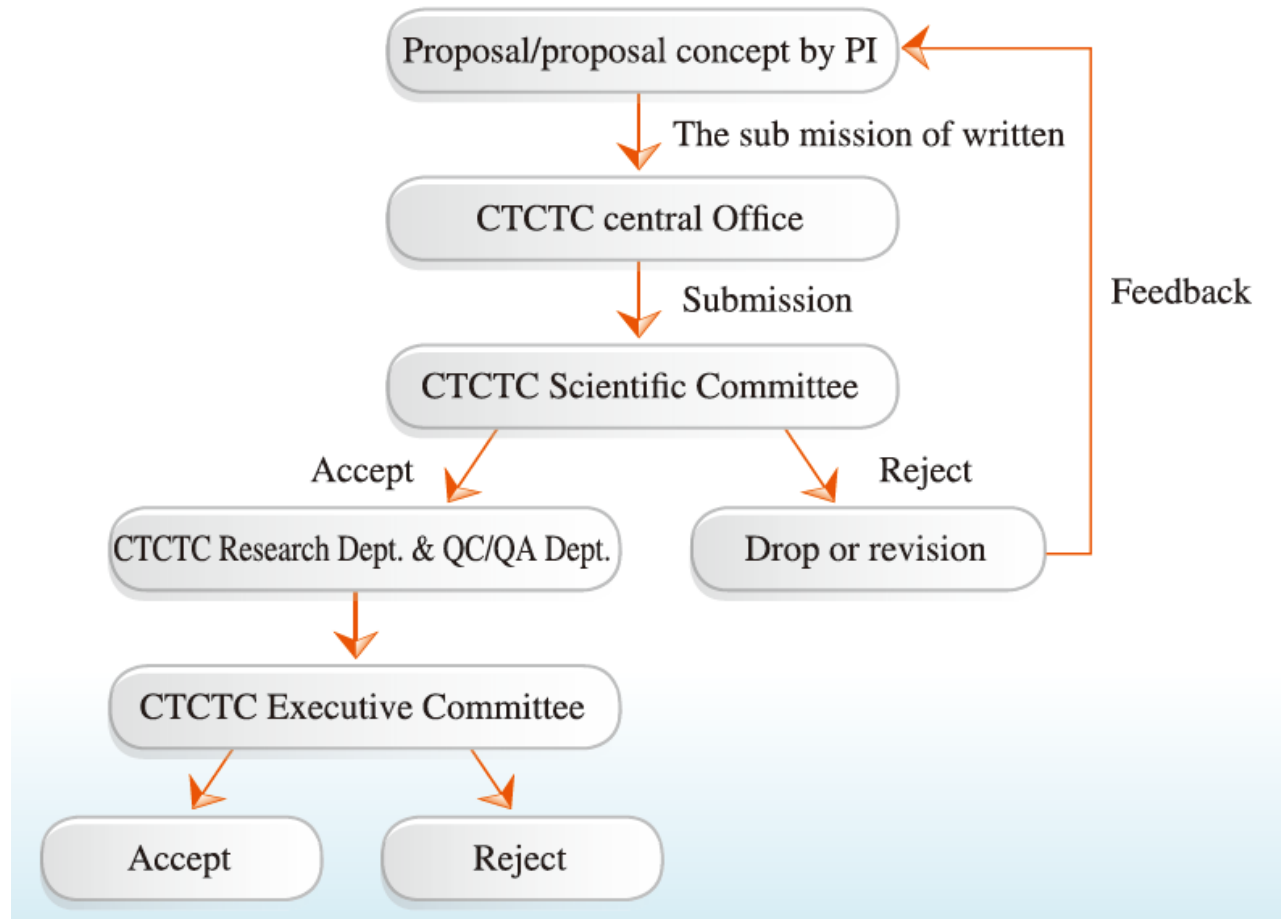
	Participating Study Sites
1	Shenyang Chest Hospital, Shenyang
2	Beijing Chest Hospital, Beijing
3	Tianjin Haihe Hospital, Tianjin
4	Shandong Provincial Chest Hospital, Jinan
5	Shanxi Provincial Tuberculosis Institute, Xi'an (not a CFDA certified site)
6	Xinxian No. 1 People's Hospital, Xinxian
7	Henan Provincial Infectious Disease Hospital, Zhenzhou
8	Wuxi No. 5 People's Hospital, Wuxi
9	Zhenjiang No. 3 People's Hospital, Zhenjiang
10	Shanghai Pulmonary Hospital, Shanghai
11	Shanghai Public Health Clinical Center, Shanghai
12	Chengdu Public Health Clinical Center, Chengdu
13	Chongqing Tuberculosis Institute, Chongqing
14	Wuhan Institute for TB Control, Wuhan
15	Changsha Central Hospital, Changsha
16	Fuzhou Pulmonary Hospital, Fuzhou
17	The 1st Affiliated Hospital of Xiamen University, Xiamen
18	Guangzhou Chest Hospital, Guangzhou (not a CFDA certified site)
19	Shenzhen No.3 People's Hospital, Shenzhen
20	Xinjiang Chest Hospital, Urumuqi



CTCTC Structure



Decision Making Mechanism



Communication mechanism

- Face to face meeting:
 - Managerial: 1/year, at China National TB Hospital annual meeting
 - Academic: 1/year, at China CMA-TB annual meeting
 - Training workshop: 3-4/year in the beginning, and current 1/year with specific focus
- Webinar meeting/training: 1/month
- CTCTC quarterly update, and annual report



On-going Studies

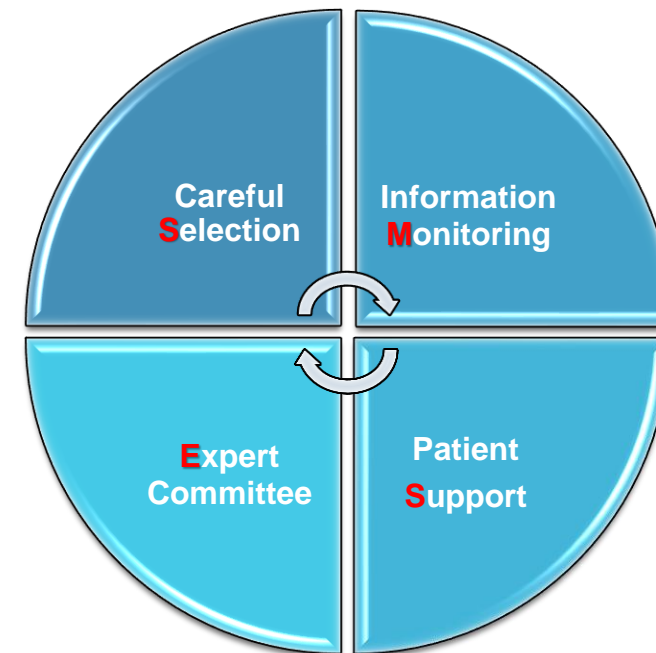
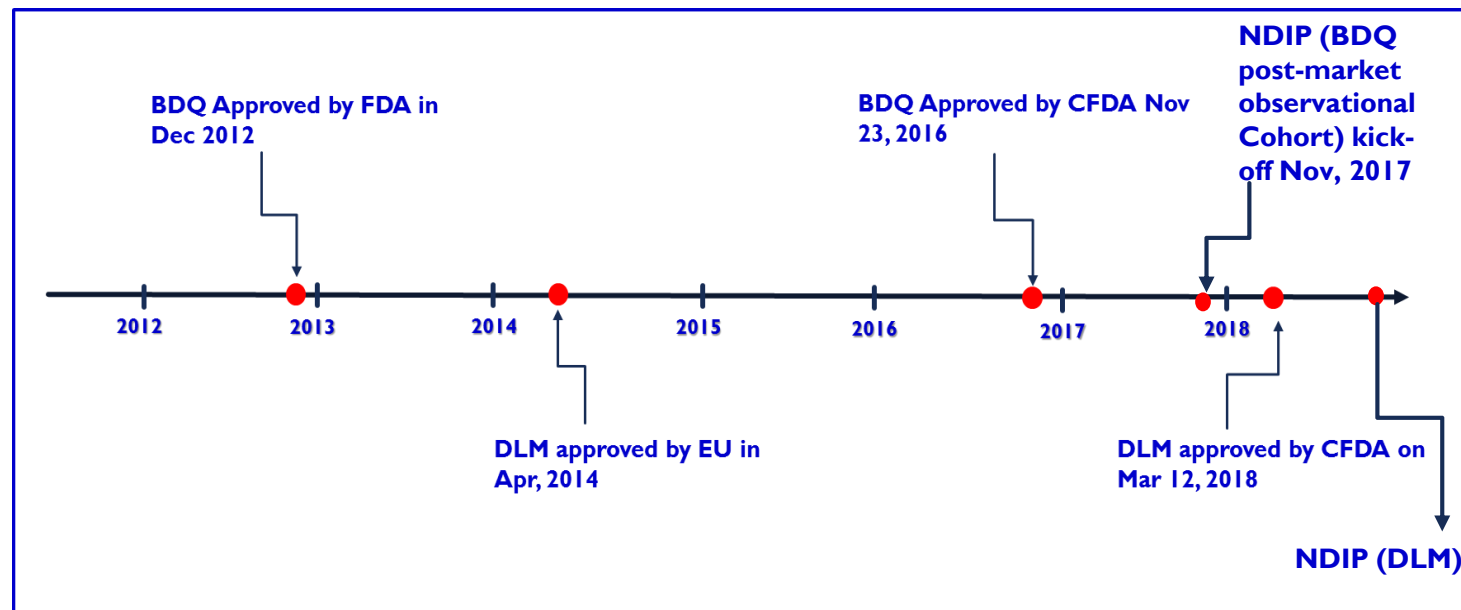


NDIP

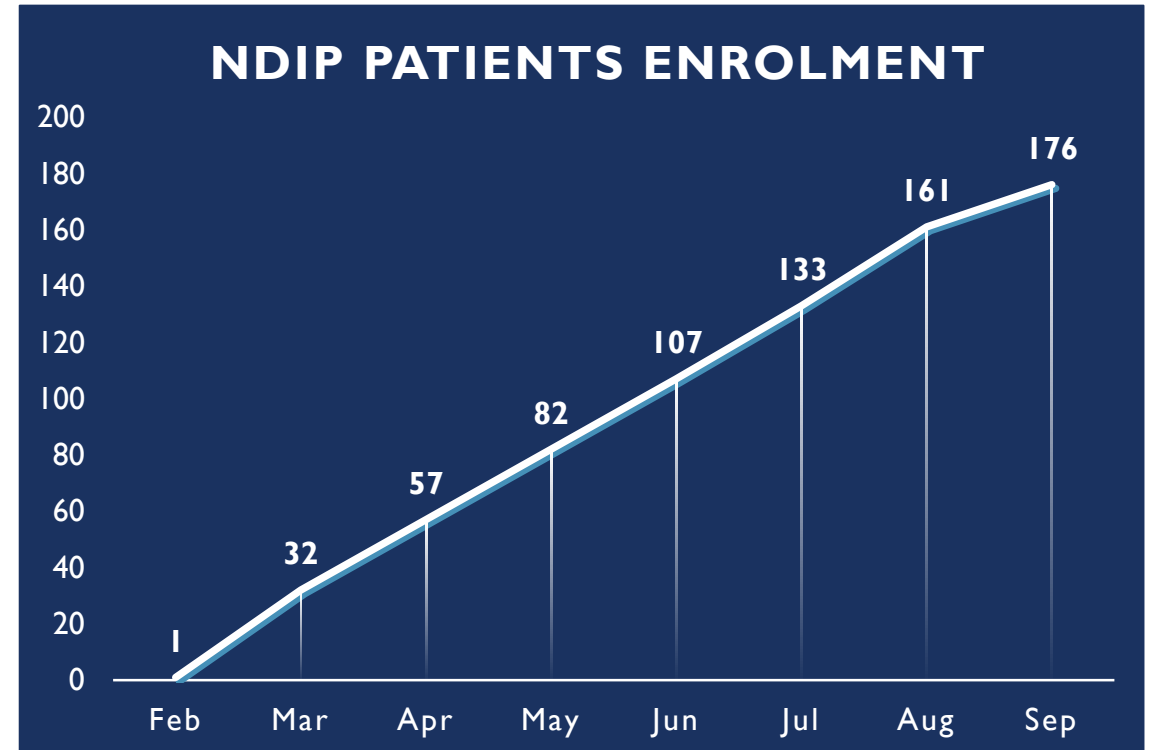
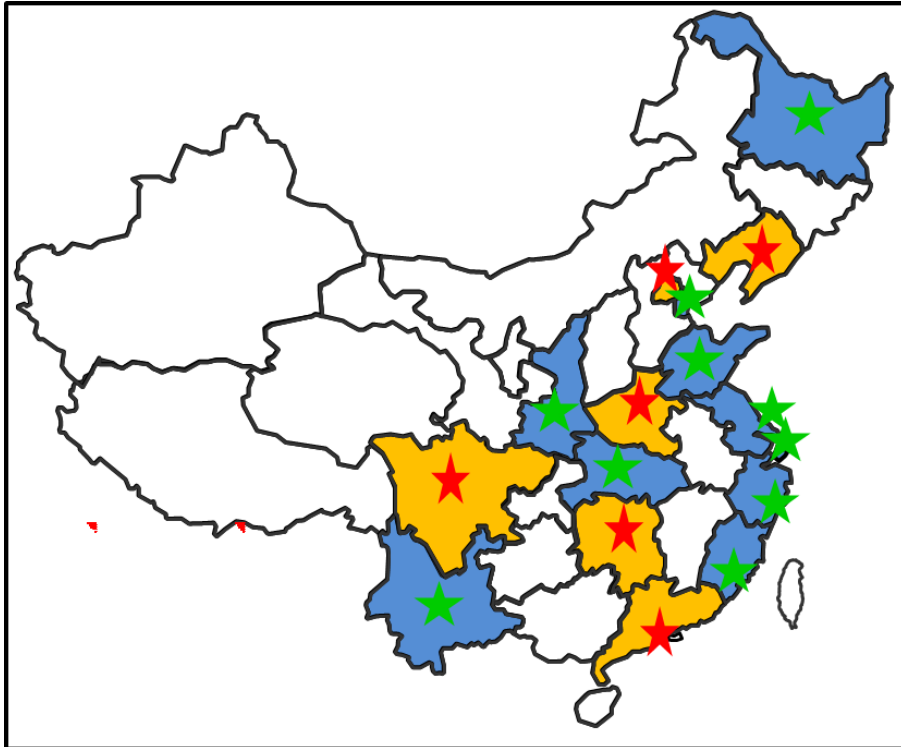
新药引入和保护项目

New Drug Introduction & Protection

S - E - M - S

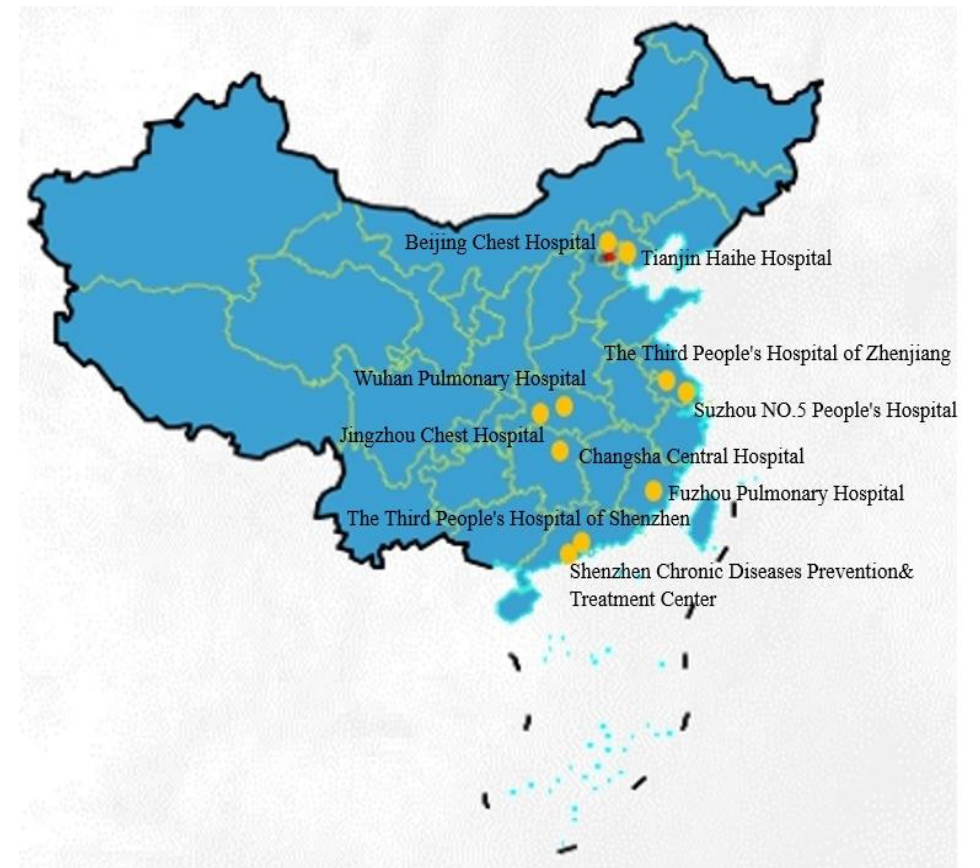


NDIP (BDQ) Sites and Patients Enrolment



On-going Studies: RePORT-CHINA

- Joined RePORT international in Jan 2017
- 10 selected sites in RePORT-China
- 93 qualified cases enrolled for Cohort A, and 896 specimens collected
- Funded locally from BJ municipal government and IATB
- Key partnerships are NIH and FHI 360



On-going Studies:

CTCTC Research Grants for Young Investigators: RI (2017)

Leading site	Research topic
Chengdu Public Health Clinical Center	Clinical features of tuberculosis complicated with HIV and viral hepatitis: a retrospective study
Ningxia No 4 People's hospital	The synergy effect of cycloserine (CS) on the therapy of tuberculosis in vitro
Shenyang Chest Hospital	Evaluation of the diagnostic value of GeneXpert MTB/RIF test in urinary tuberculosis of HIV(-) population
Beijing chest hospital	Evaluation of Xpert MTB/Rif test on centrifugal cerebrospinal fluid in the diagnosis of tuberculous meningitis
Jingzhou Chest Hospital	The synergy effect of cycloserine (CS) on the therapy of tuberculosis in vitro
Shanghai pulmonary hospital	Effects of isoniazid and rifampicin MIC on therapeutic efficacy of primary MDR-TB
Shanghai Pulmonary hospital	A novel lymphocyte transformation test in the diagnosis and prognosis of anti-TB drug induced hypersensitivity
Changsha Central hospital	The risk of extensive drug-resistant tuberculosis transmission in China.—Interview and Location of 20 patients with extensive drug-resistant tuberculosis.

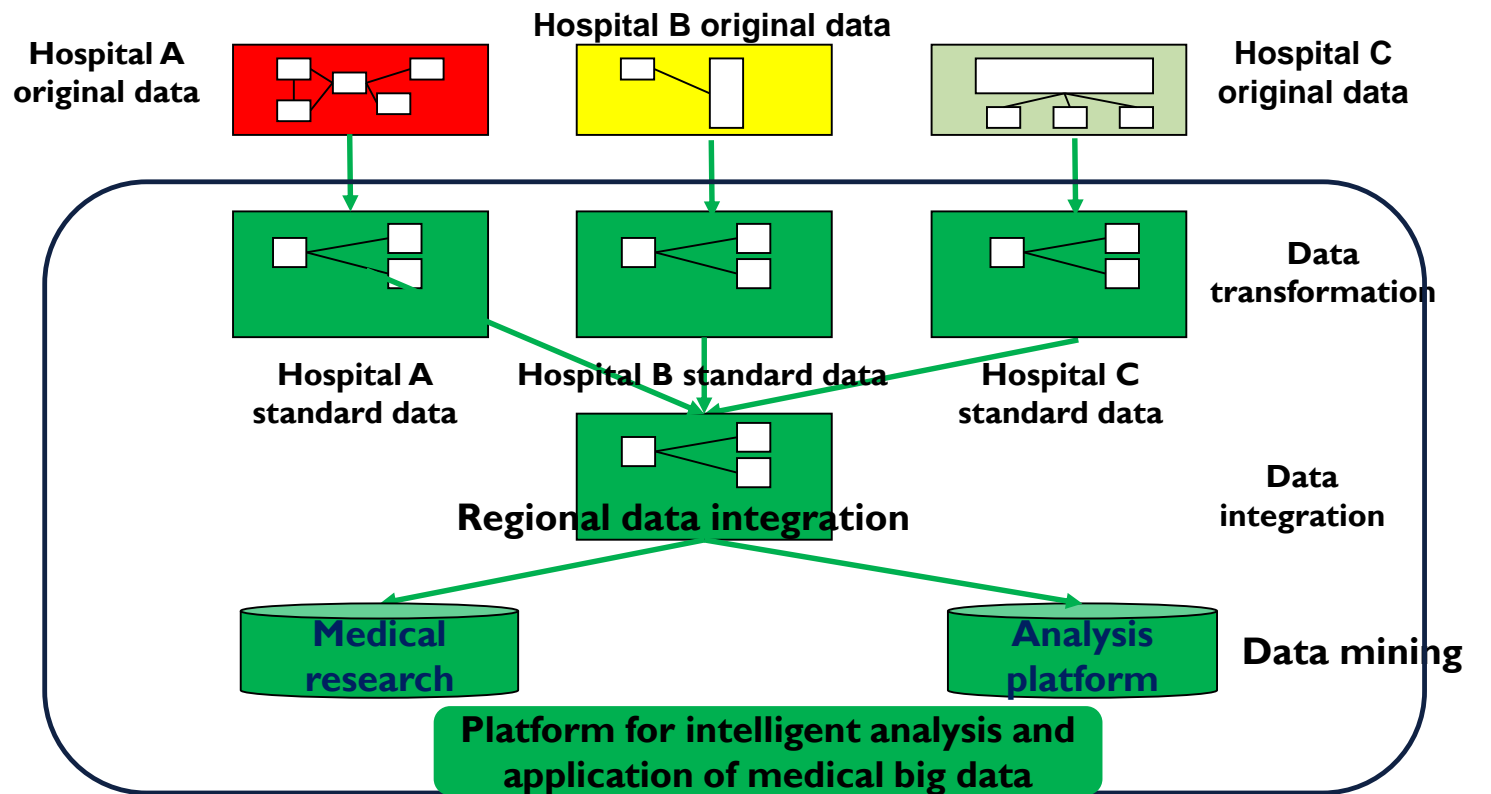
On-going Studies:

CTCTC Research Grants for Young Investigators: R2 (2018)

Leading site	Research topic
Shandong Chest Hospital	Effect of empiric anti-tuberculosis therapy on the PZA resistance in newly diagnosed patients
Beijing Chest Hospital	Application of Real-time Fluorescence Quantitative Nucleic Acid Amplification (Xpert MTB/RIF) in the Diagnosis of Intestinal Tuberculosis
Shenzhen No.3 Hospital	Correlation between linezolid serum concentration and drug neurotoxicity
Beijing Chest Hospital	Study on ototoxicity associated with anti tuberculosis injections (Am, Cpm) in patients with tuberculosis
Chongqing Public Health Center	Clinical application of overlapping extension PCR fragment sequencing for detection of drug resistance of three kinds of anti tuberculosis drugs
Tianjin Haihe Hospital	Optimization and evaluation of MALDI-TOF-MS identification method for Bactec™ MGIT™ 960 liquid culture
The Fifth People's hospital of Suzhou	Effect of fluoroquinolone exposure on detection of Mycobacterium tuberculosis

On-going Studies: Hospital data Standardization

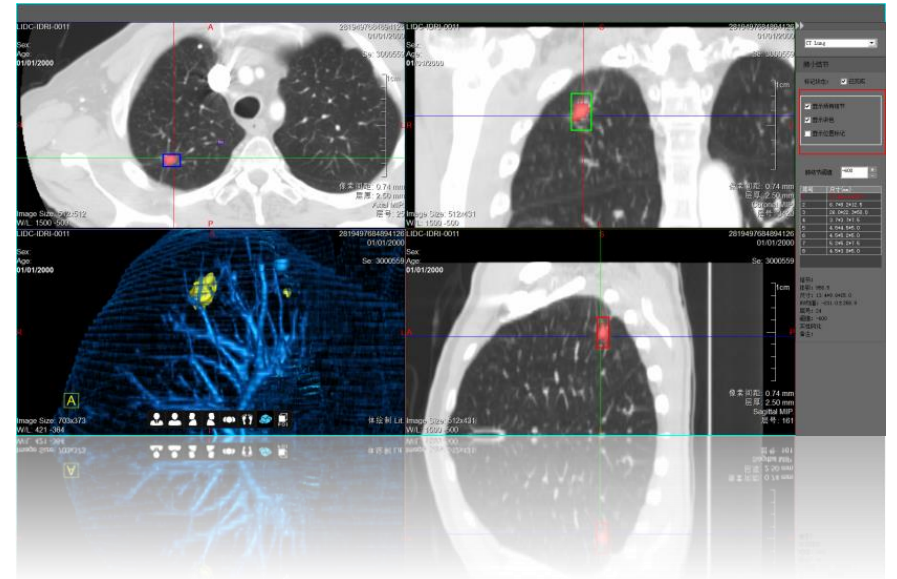
- Hospital data: large amounts, complicated, isolated and more emphasis on application than analysis
- Standardization: first step for application
- Real World Study(RWS): specific application of hospital data standardization
- By 2018: carried out by 6 hospitals



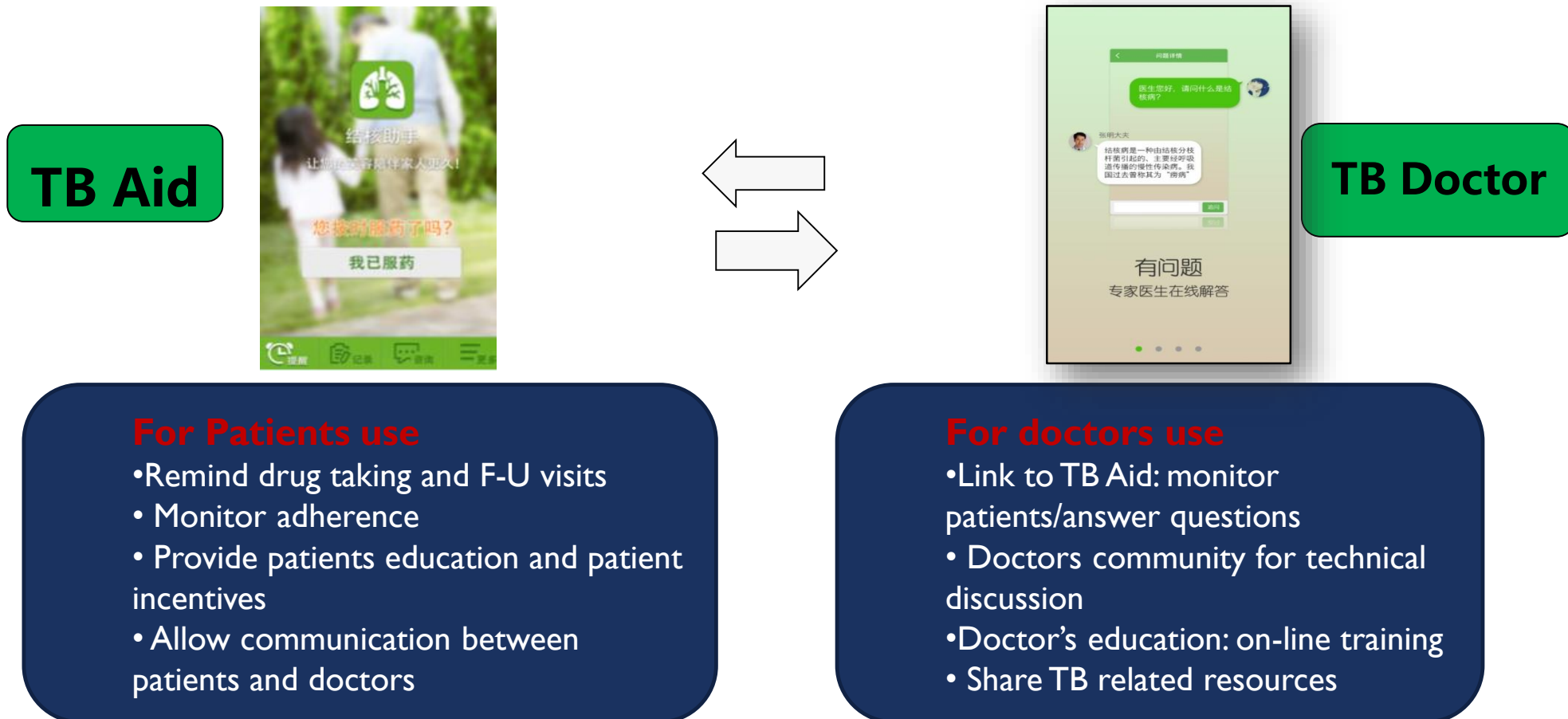
On-going Studies: Imaging Big Data

- To fill the gap on TB diagnosis at peripheral level: remote medical imaging consultation
- By the end of 2018:
 - to establish a pulmonary TB image center consist of 11 TB hospitals and 100,000 pulmonary image database
 - the design of the AI (Artificial Intelligence) image-reading software will have been finished

AI's prospect encouraging



On-going Studies: Patient management System

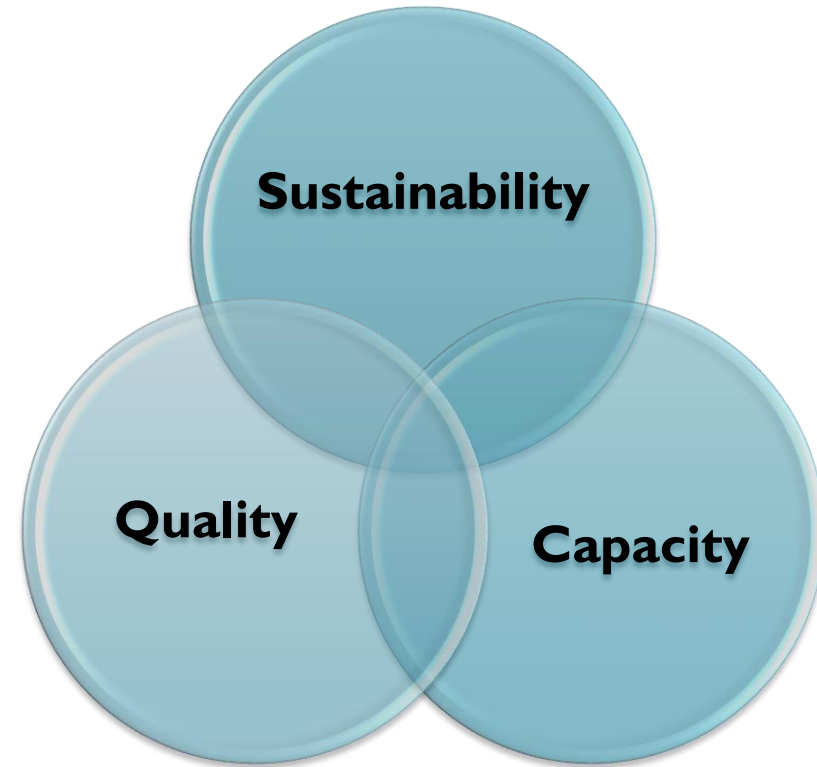


Planned Studies

Area	Description of Study	Sponsor	CTCTC sites evolved	Current Status
MDR Treatment	STREAM 2: 6-9 months treatment with/without BDQ	Union	4	Expected start in Nov 2018
MDR Treatment	DLM post-market Observational Cohort	Otsuka	TBD	Expected start in Jun 2019

Into the future:

- **Research:**
 - New drug & new regimen
 - bio-repository
 - Big-data
- **Research Team Capacity Building**
- **International cooperation**



Acknowledge:

- Strong support from NIAID/NIH, FHI 360
- Joint efforts of CTCTC member hospitals



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