

Model of interaction between China and Europe on a B&P project

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ABSTRACT

In order to help for the creation of a new China Biostatistics and Programming (B&P) team, a project has been developed in collaboration with the China team.

To initiate this collaboration, a programmer has been relocated on China site for several weeks while other programmers were on Europe site.

How to implement this collaboration:

- Determination of a training plan
- Determination of a project action plan
- Determination of standards, tools and applications used (version)
- Documents sharing (How? Where?)
- Planning of teleconferences (to take regular bearings)
- Evaluation of needs
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INTRODUCTION

The B&P Oncology department is on several sites: Us, China, Japan and France.

This paper presents the different steps of implementation of collaboration on a project between China and France.

B&P ONCOLOGY TEAM PRESENTATION

US Team

French Team

China Team

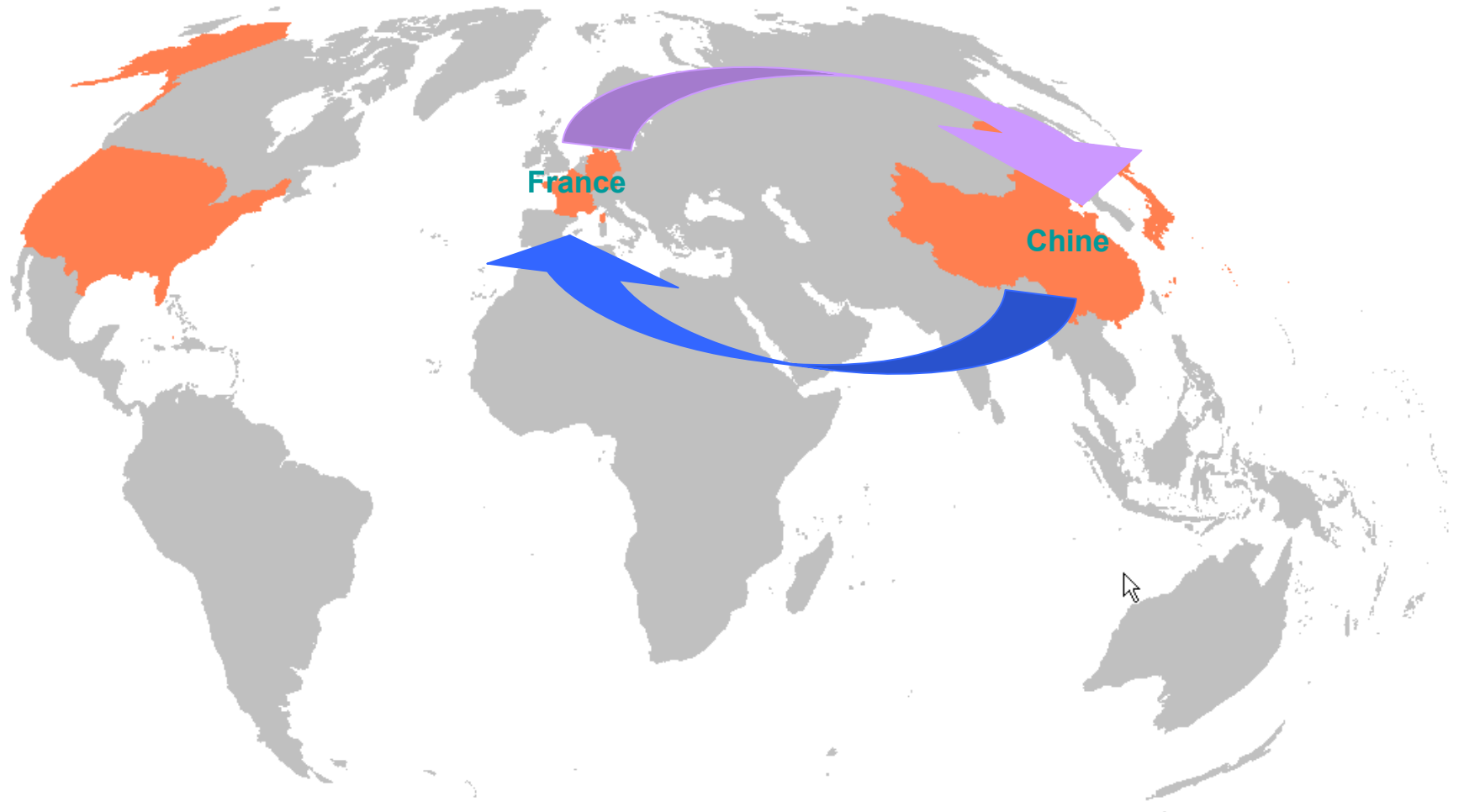
Japan Team

PROJECT PRESENTATION

The collaboration was done to set-up a DMC (Data Monitoring Committee) report of a ph III study.

The project team in charge of the programming was located in France and the China team did the validation.

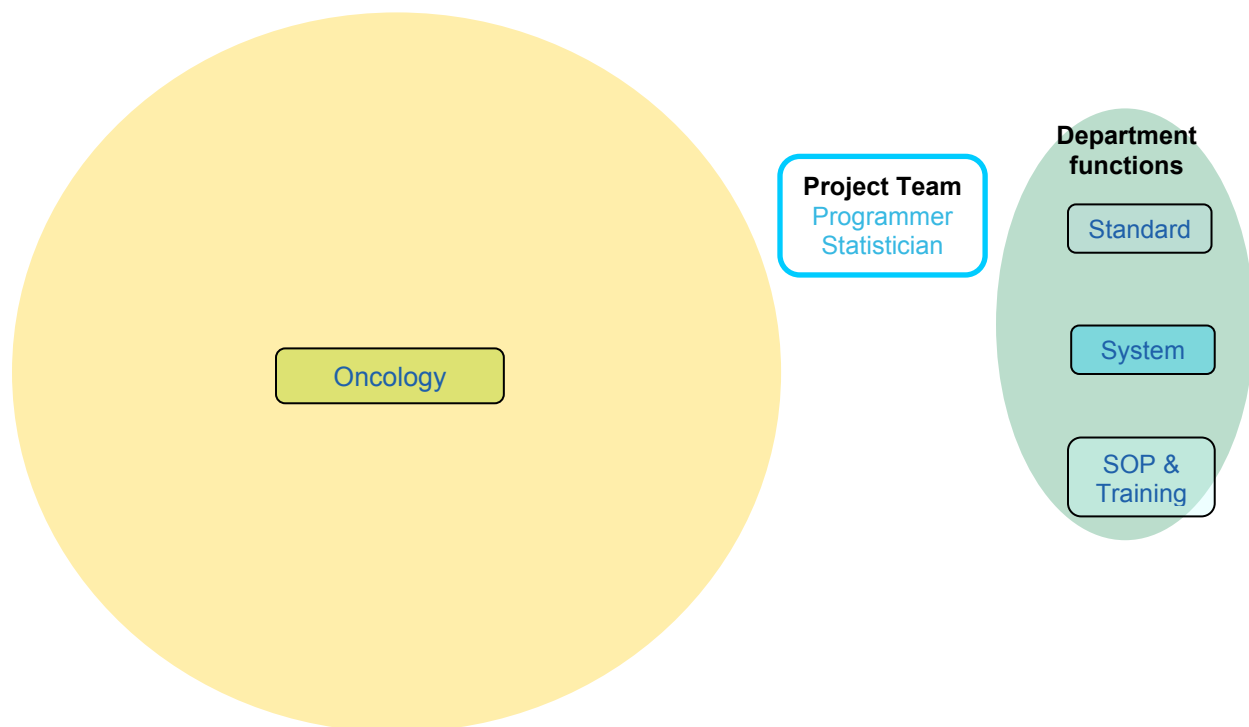
To facilitate this collaboration, a programmer was re-located on China site (Beijing) for 3 months (from June to August 2009).



PROCESS

Analysis of needs:

- System training
- Oncology training
- Project training



SYSTEM TRAINING TOOLS

Training was previously done on the system, working area, reporting tools, standards, SOP... by some members of the system team from US and France.

ONCOLOGY TRAINING PLAN

- Drug development in oncology
- Clinical Trial Endpoints:
 - Disease Free Survival (DFS)
 - Progressive Free Survival (PFS)
 - Overall Survival (OS)
- CDISC specifications
 - Analysis DataSets (ADS)
- RECIST criteria
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APPLICATION

- How to share information?
TC, documents...

PhUSE 2009

- TC organized every 2 weeks to do a status on the project
 - Excel file to share the questions, the comments... (eg excel file)
- Where?
e-room
- Input of French programmer
 - Planning coordination
- Input of programmer re-located in China:
 - Help to put training into practice
 - Support
 - Ensure the correct usage of the tools, of the interne rules....

CONCLUSION

Training a China team via a project worldwide has some advantages but that implies also some constraints at each step of the project:

+	-
Increase of knowledge	The language barrier
Learn about each other	Organization, preparation, Management of the time differences
Re-location of a French facilitate the communication and the learning	Lack of experiences of China team
The teams work closely	

However the main important thing to keep in mind is to have, now, a main contact between France and China....

CONTACT INFORMATION

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