

How to Build an “Offshore” Team with “Onshore” Quality

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ABSTRACT

In today's competitive global market, many pharmaceutical companies and CROs are building offshore clinical programming teams for various reasons. Often times, we heard cases about offshore outsourcing deals gone bad. For the past year and half, PRA Health Sciences (PRAHS) successfully build a clinical programming team through a joint venture with WuXi Apptec in China. Currently we have clinical programming teams in Shanghai, Beijing and Wuhan. They truly have become an extension of our global programming team, and enable us to provide around the clock service for our sponsors. This paper will discuss the challenges we faced and solutions throughout the process in the following area:

1. Recruitment and Retention
2. Training and Certification
3. Global and Local Management Support
4. Resourcing Process and Policy
5. Project Governance

INTRODUCTION

PRAHS and WuXi AppTec, a leading CRO with operations in China and the United States, formed a joint venture back in December 2012. Since then, we have successfully built a well-structured clinical programming team consisting of clinical programmers in 3 major cities in China. This is an “Offshore” team in terms of geographical location, but truly is an extension of our “Onshore” team. Throughout the process, we worked through many obstacles and lesson learned sessions in the areas of recruitment and retention; training and certification; global and local management support; resourcing process and policy; and project governance.

RECRUITMENT AND RETENTION

To build an offshore team or any team of clinical programmers from ground up, recruitment of well qualified applicants becomes really critical. As the CRO industry developed rapidly in recent years in China, demand for experienced programmers is extremely high, but the pool of experienced programmers is relatively small comparing to other low cost centers like India. Many times, it's a vicious war among CROs to compete for the top talent in the industry. As a result, in today's Chinese CRO market, retention of the talent and expertise is one of the biggest challenges.

RECRUITMENT

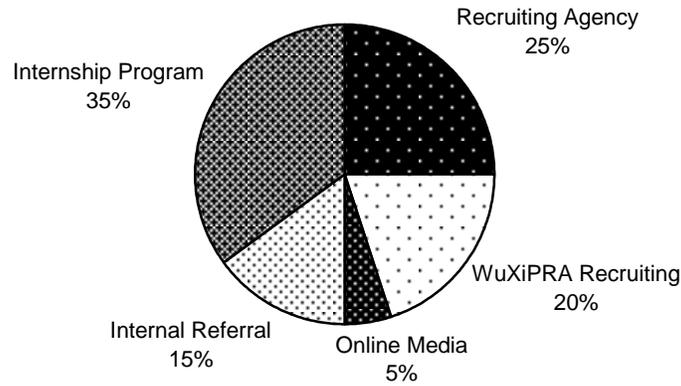
Experienced programmers are mainly recruited through recruiting agency and internal referral. In recent years, one other source of experienced programmers is programmers who currently work overseas but is seeking opportunities in their native country.

Developing a well-planned internship program has also proven to be critical for providing a stable and quality pool of entry level programmers. In order to achieve this, we established relationships with local universities to build talent and capabilities internally using existing onshore development and mentor programs.

We mainly recruit though the following channels:

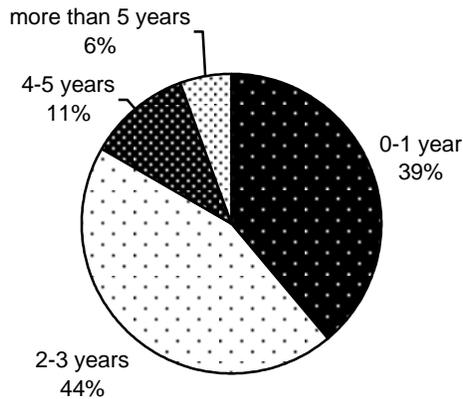
- Recruiting Agency
- WuXiPRA Recruiting
- Online Media
- Internal Referral
- Internship Program

Recruitment Channels



Clinical Programming (CP) Retention Status

Our goal is to have a blend of both experienced and internship program sourced CPs, with conversions of associate CP to CP1 at 6 months. Currently more than 60% of our offshore team has greater than 2 years' experience.



RETENTION

No one likes to be other competitor's training camp for experienced programmers. In major metropolitan cities like Shanghai and Beijing, experienced programmers often get inquiries from recruiters on a daily basis, and are offered above average competitive salaries. It's very difficult for the programmers not to get tempted. It has always been a huge challenge to maintain the talented, experienced, and yet stable team. We have been focusing our retention

strategies in the following areas:

- Clearly defined company value and culture
- Clear and focused career path
- Competitive salary and bonus
- Ongoing internal and external training
- Choose office locations close to mass transportation to ease the employee commute
- Regular leadership trips to offshore offices to show existing employees the interest in growing the office
- Identify key members and top talent as must retain
- Increase responsibilities for team members with high performance and high potential based on their interest

By doing this, we have been able to maintain our turnover rate at about 20%.

TRAINING AND CERTIFICATION

One key factor for ensuring the success of this team is our well designed training program and structured certification process. All new hires are required to go through PRA training and certification prior to working on PRA global projects.

TRAINING

We provide two types of training for new hires depending on their prior experiences:

- Experienced Programmer Training
- Entry Level Programmer Training

Experienced Programmer Training

Experienced programmer training is designed for programmers with more than 2 years of programming experiences and training will focus on PRA SOPs, PRA system, PRA reporting macros, PRA internal data conversion tool, CDISC standards including SDTM and ADaM, etc. Since WuXiPRA programmers will be working on the same SAS server as PRA onshore programmers, this will ensure that WuXiPRA programmers are well qualified to work on PRA global projects following PRA global SOPs and standards. Duration for this type of training is typically 2 weeks.

Entry Level Programmer Training

Entry level programmer training is designed for college graduates with no prior experience in Pharmaceutical industry and SAS programming. Other than everything mentioned in the experienced programmer training, they will be trained on everything from drug development process, how to program in SAS, how to program tables, listings, and figures, how to program SDTM and ADaM, etc. Duration for this type of training is typically 3 to 6 months.

CERTIFICATION

After completing the required training, all WuXiPRA new hires are required to go through the certification process in order to work on PRA global projects. This serves as the gate keeper for working on global studies. Certification process includes but is not limited to the following:

- Daily Interaction between Trainers and Trainees
 - Closely monitor trainees' response and feedback during training
 - Personality/Team Player
 - Multi-tasking Skills
- Performance on the Practice Study
- One-on-one Interview
- Clinical Programming Exam
- English Skills, both Verbal and Written

- Past Education and Employment Background

Decision will be made based on the combined assessments from the evaluation performed on the items listed above. On average, we are able to certify around 60% of the CPs who attend the training within each batch.

ONGOING TRAINING

Once clinical programmers pass the certification, we typically have them work on routine work such as simple safety tables and listings, or SDTM, and gradually increase the complexity of assigned work. This is also the same approach we took when we first put together the WuXiPRA CP team. We started by giving routine work to our offshore team while keep complex programming onshore. As the offshore team grows in their skillsets, workloads start to shift. By providing ongoing training, WuXiPRA CP team now is able to do all of the following activities:

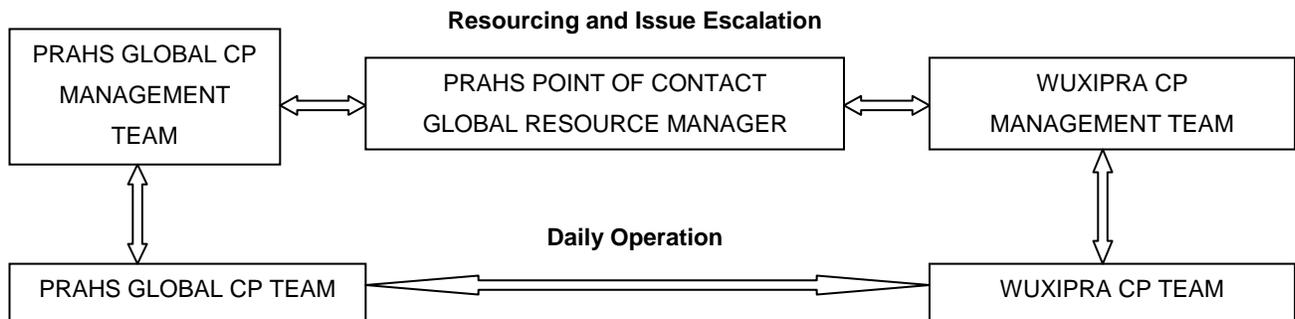
1. SDTM and ADaM Specifications
2. Production of SDTM, ADaM, and TFLs
3. QC of SDTM, ADaM, and TFLs
4. Lead Projects
5. Unblinding Activities
6. DSUR and DMC Outputs

We have really seen WuXiPRA CP team grow into a strong extension of PRA's global CP team. They are not only able to provide high quality outputs within timeline, but also stay in budgeted hours as well, which is very critical to the CRO business model.

GLOBAL AND LOCAL MANAGEMENT SUPPORT

MANAGEMENT TEAM STRUCTURE

Global management support is proven critical so far in the success of our offshore programming team. Here is a flow of how the onshore team interacts with offshore team.



RESOURCING PROCESS AND POLICY

PROJECT WORK INITIATION

- PRA Functional Managers (FM) and Global Resource Manager (GRM) identify potential project work for WuXiPRA staffing.

PROJECT WORK COORDINATION

- WuXiPRA FMs coordinate project work with local team leads and CPs
- WuXiPRA CPs work directly with PRA internal teams

PROJECT GOVERNANCE

- WuXiPRA FMs perform gate-keeper review
- Joint weekly project progress review to closely monitor progress and quality
- Joint bi-weekly management meeting to closely monitor time and financial performance
- Joint quarterly performance review to evaluate programmers' performance on PRA projects
- Questionnaire for collecting performance feedback on communication, timeliness, technical skills, budget management, process and document compliance, and overall quality for all studies

CONCLUSION

For the past two year, WuXiPRA has truly become an extension of our global programming team. As the regulatory environment keeps on improving in the Asia Pacific region, it's critical for top CROs like PRAHS to have a strong representation in countries like China. By having this well-structured and highly qualified offshore CP team, this not only enables PRAHS to meet our customer's strategic needs in Asia-pacific region, but also enables us to provide sponsors 24-hour around the clock service.

CONTACT INFORMATION

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