Competent statistical programmer: Need of business process outsourcing industry

Over the last two decades Business Process Outsourcing (BPO) has evolved as much mature practice. India is looked as preferred destination for pharmaceutical outsourcing over a cost arbitrage. Among the biometrics outsourcing, statistical programming and analysis required very niche skill for service delivery. The demand and supply ratios are imbalance due to high churn out rate and less supply of competent programmer. Industry is moving from task delivery to ownership and accountability. The paradigm shift from an outsourcing to consulting is triggering the need for competent statistical programmer. Programmers should be trained in technical, analytical, problem solving, decision making and soft skill as the expectations from the customer are changing from task delivery to accountability of the project. This paper will highlight the common issue SAS programming service industry is facing and skills the programmers need to develop to cope up with these changes.

Key words: Business process outsourcing, statistical programmer, skill

Pharmaceutical outsourcing

Reduced international trade barriers and improved telecommunication and information technology (IT) capability over the past decade has led to a situation where organizations across the world are increasingly interlinked with each other. This has resulted in intense global competition, challenging business managers across the world to find ways to reduce the cost of conducting business and accessing global resources in meeting the need of global markets. Over the last two decades business process outsourcing (BPO) has been catering to various industries such as Retail, Insurance, Mortgage, Banking and Finance, Healthcare and Pharmaceutical, Telecommunications, Technology, Travel and Hospitality and much more. The Pharmaceutical outsourcing has grown tremendously in last one decade. The top 10 Pharmaceuticals have outsourced the Pharma development to the BPOs and Contract Research Organizations (CROs) in India. The key challenge of Pharmaceutical Industry are limited pipeline in drug development, reducing cost pressure, time to market, competitive pressure, changing regulation and patent expiry. BPOs and CROs have played a vital role in the drug development from simple task such as data cleaning, data processing to be complex of medical writing and statistical programing. The BPOs scalability and CROs domain centricity has played a key role to develop the Pharma outsourcing business in India. The crux of competition is to bring the drug in the market faster and cheaper (investment cost) and hence cost arbitrage is one of the key parameter of the outsourcing by these companies. BPOs started with transactional services such as data entry and scaled to functional service provider model. 10 years down today customers are looking for transformation and Innovation in the services. A big buzz of “value based outsourcing” is the talk of the Industry.
The competition has made the customers more demanding where learning from the competition is a big advantage.\cite{3} In today’s outsourcing world customers are looking for global presence (follow the sun) for able to deliver the services globally by same standards. Big players such as Accenture, Cognizant, TATA Consultancy Services, Wipro, Infosys, Parexel, SIRO ClinPharm, ICON, PharmaNet and Quintiles etc., are servicing the Pharmaceutical and Healthcare customer to a large extent. Clinical services such as clinical data management, pharmacovigilance, regulatory, clinical operation, statistical programming and analysis, medical writing is commonly outsourced. Among these, statistical programming and analysis domain required a niche skill for service delivery. This paper will discuss about the challenges the programming industry is facing and what is expected from a competent programmers.

**STATISTICAL PROGRAMMING: A NICHE SKILL DOMAIN**

Statistical Programming and Analysis is considered as niche skill domain and require competent SAS programmer for services delivery. This is primarily because historically there have been few formal training programs for Clinical SAS programmers. As a result, most statistical programmers have to learn about clinical trial analysis and reporting on the job. Clinical programming is not transactional process however is considered as a data science which required understanding of protocol, endpoints, design, data structure and standards. The role of statistical programmers is to convert the raw data to meaningful information for the use of statistician and clinician. This may involve importing and exporting data, working with other IT professionals on site and at other companies, deriving variables and creating analysis data sets and creating clinical study report materials consisting of tables, figures and listings. Since these days, BPOs and CROs are servicing this niche domain to a large extent, the expectation from organization and customer is that statistical programmer should be competent by clinical research knowledge, SAS procedure, soft skill, planning and organization and ability to deliver the projects in the tight timeline with quality.

**KNOWLEDGE AND SKILL-A PARADIGM SHIFT**

BPOs has started with simplest process of data entry and scaled to niche domain such as programming and medical writing and complete end to end value sourcing. With the niche domain outsourced, the skill requirement of this industry has seen the paradigm shift. In the programming space some of the expectations from the customers are listed.

- Independent working (less oversight from the customer)
- Change in regulatory need (how BPOs adapt to change in regulation)
- Knowledge of clinical trial design (end to end value chain)
- Complex clinical design and need for complex procedure
- Analyst mindset (planning, execution, problem solving and decision making skill)
- Customer interaction (global and virtual)
- Quality and timeline (first time right approach with agreed timelines)
- Accountability and ownership (moving from services to partnership mindset)
- Transactional to transformation (from protocol to data base lock).

Today’s programmers are expected to have good blend of Technical, Communication and analyst mindset skill. Industry is witnessing the change and hence most of the organization is realigning the training strategy to meet the customer demands.

**ATTRITION - COMMON INDUSTRY PROBLEM**

With an employee turnover in the Indian offshoring sector ranging over 40%, it is not surprising to find attrition being cited as one of the main causes of concern by the customers.\cite{1} It has attracted the attention of the top management of both clients and service-providers, who are now viewing this as an area of strategic importance, rather than an operational issue. The PricewaterhouseCoopers\cite{3} survey states that survey three prime reasons to explain the high-attrition phenomenon, which include perceived lack of growth opportunities in the organization, migration to more stable work environments and most importantly, search for higher pay-scales. Attrition is the common problem of the industry is facing today. Most of BPOs has reported 20% year-to-date attrition. When demand is high and supply of competent programmer is less, attrition in this domain make the service delivery more difficult. Even programmers are encasing the opportunity due to very high demand. It is has been seen most of the time the Talent Acquisition Team struggling to get the right candidature. The time organization loose the competent programmer, it takes lots of time to get the replacement with similar skill. I have witnessed the number of resume sourced and people selected which account not more that 8-10% of employability. The churn rate is very high and the employability rate is very low which always keeps the programming skill in demand. In spite of on boarding experience programmer sometimes the training duration...
is the barrier to make the programmer productive. Each customer has a different training plan which ranges from 4 to 16 weeks of training to certify the programmer. One of the reason industries is seeing the high attrition is unrealistic aspiration of the programmers. After spending 4 years in the project a natural aspiration to become team leader and get rid of all the programming activity and move on the ladder to become a people manager. Most of customer is demanding senior programmers with 8-10 years of hands on experience, not sure how the industry will meet this requirement falling to do this may lead to loss the business.

**DEMAND SUPPLY EQUATION**

The demand and supply ecosystem need to be balance and several factors have contributed to make this unstable. Lack of Industry-Institute collaboration is one of the key factors. Graduates and post graduates syllabus should be in sync with the need of industry. All the theory and practices taught in the academia should be need based. How many statistics graduates have learned SAS while studying? Most of the statistical programmers who end-up working in clinical trial analysis happen upon the field by accident. The Universities should move from conceptual training to practical based training. A working committee of Academia and Industry (Industry Institute Partnership Cell) should meet on periodic basis to review the changing scenario and need of the industry. Such discussion will help to devise the syllabus which will be 10 years of ahead the industry will need.

Students should be encourage to take the internship in the relevant industry they belong, at the same time industry should make provision to induct the students. One of the important factor have impacted ecosystem is geographically skewed. Industry has witness in last 5 years the number of programmers joining the BPO belongs to South part of the India. Hyderabad has become a destination for human resources to source the candidate. We have handful of competent programmers in industry and everyone is eyeing the same pie, leading to attrition. Industry should start thinking of freelance options for the programmers and or working from home option. Data security will be big concern for such options but with this growing technology this can be worked out. Country like India which is culturally aligned, empowering the female programmers to work from home will help to reduce the attrition and meet the industry demand. In the West, we will find most of contractors in the organization are working from home. I agree this required vigilance both from data security and people management. As discussed above most of programmers want to move to management ladder and get rid of hands on programming, which creates a huge demand of experience hands on programmer in the country. The total count of Statistical programmer in India (servicing BPOs, CROs and Captive units) will be around 1000-1200 and 50-60% of these are competent programmer. Every organization wants these competent statistical programmers on their project and hence the demand is high.

**COMPARISON OF EAST VERSUS WEST**

The comparison of East versus West will help the readers to understand the difference while working with programming community of the west [Table 1].

All the above points discussed are issue the industry is facing today. Let us see now what makes the programmer competent. Since the need and expectation is very high, programmers should focus and work on the below points to become more competent and at the same time training plan should also be in sync with this.

**WHAT MAKES A PROGRAMMER COMPETENT?**

Let us see now what makes programmer competent? The programmer should have blend of all below attributes which makes them successful. Today’s pharmaceutical customers are looking for good blend of SAS technical, clinical trial information, planning and execution of the task, problem solving and decision making skills and much more. Soft skill are in demand to ensure programmer have requisite skill to communicate with the onshore team. Below are the attributes which makes programmer competent.

- SAS technical skills
- Clinical trial understanding
- Basic understanding of statistics in clinical trial
- Industry data standards and guidelines
- Analyst mindset (planning, execution, problem solving and decision making skill)
- Soft skill (communication skill and basic etiquette)
- Industry collaboration (conferences, microblogging sites etc.).

**Table 1: East vs. West comparison**

| East                                      | West                                      |
|-------------------------------------------|-------------------------------------------|
| Theory based learning (concepts)          | Practical/application based learning      |
| Therapeutic area (diverse)                | Therapeutic area focus                    |
| Continuous learning curve (less culture)  | Continuous learning curve                 |
| Stay with project for long time (no)      | Stay with project for long time           |
| Attrition (high)                          | Attrition (low)                           |
| High end exposure (low)                   | High end exposure (high)                  |
| Career track (functional or management)   | Career track (functional and management)  |
| Experienced talent pool (low)             | Experienced talent pool (high)            |
| Transactional services                    | End to end exposure                       |
SAS technical skill
Today’s SAS programmer should be well-skilled with base and advance SAS procedures used in the clinical trials. Programmer should be competent to apply these procedures by writing the right data steps using input data to get the desired output. Most of the time we experience that an even certified SAS programmer is unable to apply the SAS knowledge on the clinical data. Understanding the data structure and data visualization is a very vital skill. Before writing the programs, a programmer should visualize the output based on the data structure.

Clinical trial understanding
Working on few studies is not the boarding pass for a programmer claims. A competent statistical programmer will takes time to understand the subject matter. If you were going to perform open-heart surgery and you were handy with a knife, you would not just roll up your sleeves and get to work. You would get formal training and obtain a medical degree first and hence that you understood what you were doing.[5] The same can be said of SAS programming in the pharmaceutical industry. Just because you are a SAS expert does not mean you know all there is to know about a particular drug or device or the disease state it intends to cure.

Programmer should read the clinical protocol to understand the clinical design, randomization schedule, per protocol analysis, statistical analysis, primary and secondary variable etc., The statistical analysis plan (SAP) is a very detailed document, describing how the clinical trial data will be analyzed. The SAP describes what inferential analyses will be done, defines the study population, presents data windowing or other special data handling rules and often includes draft output shells that show precisely what tables, listings and graphs will be provided in the reporting. The SAP is where the majority of your work is defined. Thus, you need to understand the SAP in exquisite detail and hence it is beneficial to study it well in advance of programming.

Basic understanding of statistics in clinical trial
In-depth knowledge of statistical methods is not necessary unless you are designing a trial or analyzing the data yourself, but because statistical methods are discussed in most study protocols, it is important to understand the basic terminology and concepts involved. Programmers should be introduced to basic statistical concepts, such as hypothesis testing, the meaning of P value and power determination. Other concepts with particular relevance to clinical research design and monitoring such as the importance of randomization and randomization procedures, stratification, crossover designs. As most of the statistical programmer do not belong to statistics back ground and the task they perform are reviewed by the Statistician and Clinician. If Programmer knows the basic of statistics this will help a lot in the job. Programmer should understand the need of the reports and the values in this. Truong have published a good paper on “Clinical Trials Terminology for SAS Programmers”[6] and encourage the reading. Basic of statistics should be part of the training curriculum and also should run the refresher course.

Industry data standards and guidelines
Clinical Data Interchange Standards Consortium (CDISC)[7] as one of new data standards for clinical development has been developing for last 6 years. Due to the core concept of open, multidisciplinary nature, its sponsorship, membership and participation have rapidly expanded across various organizations in the US, Europe and Japan. Food and Drug Administration (FDA) has appointed Liaisons to CDISC and completed a pilot study on patient profiler reviewing for electronic submission by using CDISC standards. With the recent publications of the FDA guidelines for e-submissions, they require more data standards than ever before so the new required deliverables, such as define.pdf and blankcrf.pdf, etc., can be clearly and conveniently provided to agency for reviewing.

Knowing CDISC is the added advantage for the programmers today. Most of the BPOs have introduced CDISC in the training curriculum to make sure people are exposed. Programmers are encouraged to be part of such forum discussion or workshop with FDA representative. Victor Sun in his article “CDISC: Why SAS Programmers Need to Know”[8] has discussed the need to know the industry standard to the programmers.

Analyst mindset
This is Big Buzz in industry these days or I can say this as voice of industry. Gone are the days when industry was looking only for SAS skills. Past few years the expectation from the programmer has changed. Ross and Ryan from Roche products have delivered good thoughts in PhUSE conference held on 2010.[9] They states that The “analyst mindset” involves a balance of many skills, but here are 4 we believe particularly important viz., communication, planning, problem solving and decision making. Further states that implementing the “analyst mindset” can help ensure we make the most efficient use of time and resource, not only for us but for the sake of the drug projects.

Soft skill
Soft skill plays a very vital role to the programmers. They are expected to updates the onshore team on the projects status draft the issue log and discuss the issue with the Lead Programmer or Statistician. Programmer should be skilled...
to articulate the issue and seek required support from the project team. Some of the Organization even conducts voice and accent training to ensure proper communication. Even culture orientation training to the programmer will help based on the geography they are servicing. Talent development team of the Organization continues working with the employees for soft skill development such as business communication, culture awareness etc.

Industry collaboration
This is the era of networking where we need to connect to the world to know the industry challenges, solutions best practice in the industry. Confining the programmers in the development center will not help; they should be encouraged to meet the programming fraternity through virtual world, micro blogging or conference. PhUse\(^{10}\) gives a good platform for all levels of the programmer to exchange the view and share the best practice. A PhUse society is developing toward a more collaborative virtual organization where members will be sharing, learning and advancing throughout the year beyond the annual conference. Those discussion clubs will be the opportunity to discuss face to face with all the mail actors (sponsor, CROs, consultancies, regulatory agencies, software vendor etc.) the challenge and opportunities our industry poses and offers for the future. Some of the domestic collaboration like Indian Association for Statistics in Clinical Trials\(^{11}\) is good forum for budding programmers to exchange the view.

CONCLUSION
Seeing the challenges that India is facing in the SAS skill across the organization, China is becoming a destination for most of the pharmaceutical customer to either outsource or start the captive. The Organization will have to invest in the competency development to the existing SAS programmers to meet the future need. Programmers also need to stay with the project for the longer duration and learn and practice the attributes discussed in this paper. The future hold true for the organization who invest in people for competency development, retain the programmer through career track, have global presence and one global standard of delivery through rigorous metric approach.

REFERENCES
1. The evolution of BPO in India. PricewaterhouseCoopers. Available from: www.pwc.com/images/tech/BPOinIndia.pdf.
2. Zhang J. New global pharmaceutical outsourcing trends, pharmaceutical online. Available from: http://www.pharmaceuticalonline.com/doc/new-global-pharmaceutical-outsourcing-trends-0001. [Last accessed on 2014 Mar 4].
3. Srinivasan S. Enhancing global competition in BPO: What India should do? Available from: http://www.dspace.iimk.ac.in/bitstream/2259/489/1/.
4. Attrition rate up 55% in BPO sector - Indian Express Available from: http://www.indianexpress.com/news/attrition-rate-up-55–in-bpo-sector/776190/.
5. Shostak, Jack. 2005. SAS® Programming in the Pharmaceutical Industry. Cary, NC: SAS Institute Inc.
6. Truong S. Clinical Trials Terminology for SAS Programmers. Fremont, CA: Meta-Xceed, Inc. Available from: http://www.lexjansen.com/pharmasug/2004/tutorials/tu03.pdf.
7. Clinical Data Interchange Standards Consortium Available from: http://www.cdisc.org. [Last accessed on 2014 Mar 4].
8. Sun V. CDISC: Why SAS® Programmers Need to Know. East Hanover, NJ: Novartis. Available from: http://www.lexjansen.com/pharmasug/2003/tdacompliance/tda055.pdf. [Last accessed on 2014 Mar 4].
9. Farrugia R, Copping R. The analyst mindset in statistical programming. Roche Products Ltd. Available from: http://www.phusewiki.org/docs/2010/2010\%20PRESENTATIONS/PD03.pdf. [Last accessed on 2014 Mar 4].
10. Pharmaceutical users software exchange. Available from: http://www.phuse.eu/. [Last accessed on 2014 Mar 4].
11. Indian Association for Statistics in Clinical Trials (IASCT). Available from: http://www.iasct.net/.

How to cite this article: Khan I. Competent statistical programmer: Need of business process outsourcing industry. Perspect Clin Res 2014;5:95-9

Source of Support: Nil. Conflict of Interest: None declared.