

The 3 Year Obsession: Length of experience the sole determinant of competence?

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Note

The research presented in this discussion is based solely on the authors' experiences with the Cytel India team.

Experience can be built Experience is important..



Agenda

- Introduction
- Key requirement of sponsors
- Problems with availability of skilled resources
- Methods to bridge the gap
- Evaluating effectiveness
- Challenges
- Conclusion

Introduction

- Functional service providers (FSP) for outsourcing ventures
- Key requirement: Quality and accountability
- A well trained and skilled programming unit is the core asset
- Yardstick of capability: Years of experience
- Settle on numbers like 3 or 5 years

Experience Matters



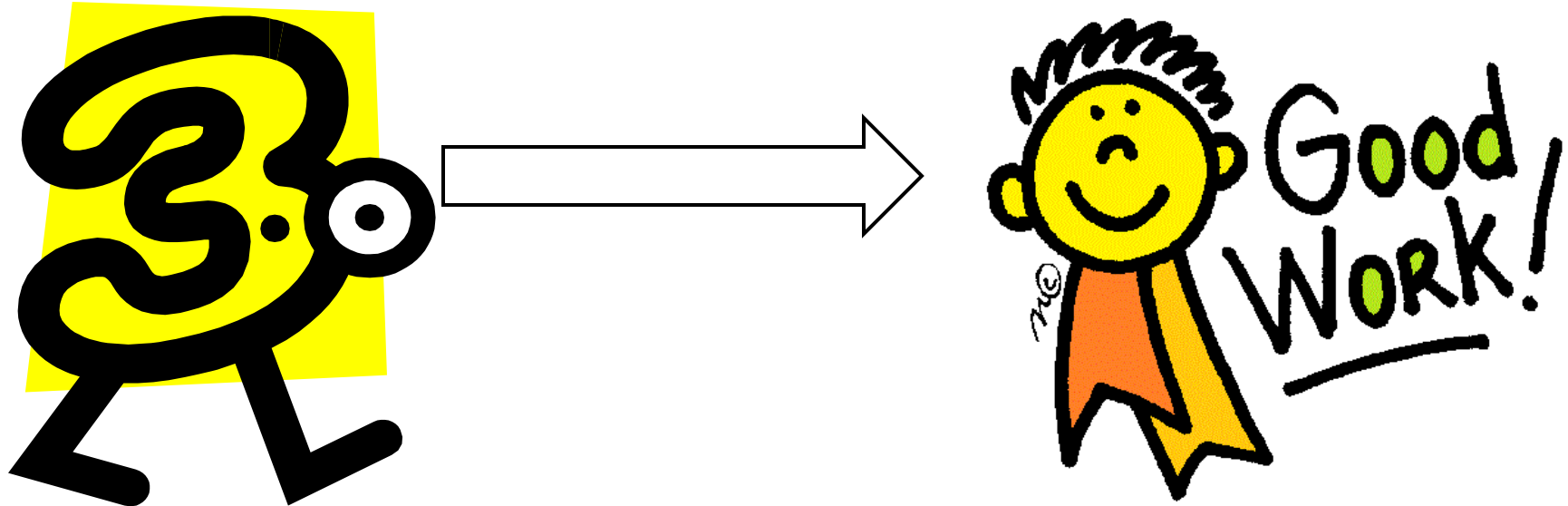
- Fewer resources
- High productivity
- Reliability
- Expected quality

General Perception

- Higher educational degrees but limited skills
- Attitude: Almost finished is good enough
- Panic button pressed too late
- Afraid to question authority/seniority
- Impact of timelines not understood

Our understanding from some of the evaluations we received

Perception about experience



**After 3 years :
Rating of 3 on a scale of 1-5**

Challenges for FSP teams

- Clinical research programming in its nascent stages
- Clinical trial programming not a popular career option yet
- Scarcity of good educational institutes

Challenges for FSP teams (contd.)

Type of
programming
handled

Sponsor team: Efficacy and complex coding

FSP team: Standard safety and simple

Cross functional
interaction and
decision making

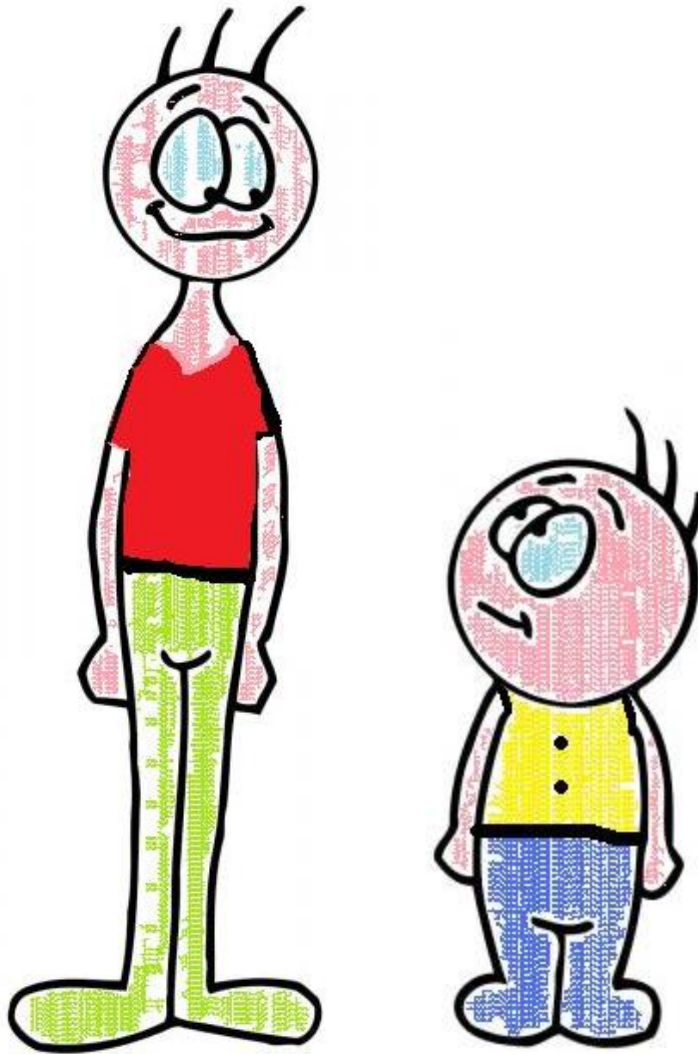
Sponsor team:

- 1. Interacts with cross –functional teams**
- 2. Participates in decision making process**

FSP team:

- 1. Interacts with programming team**
- 2. Gets informed about decisions**

Challenges for FSP teams (contd.)



- Limited exposure
- Lack of a forum to discuss study details
- Less proactive without addition of individual input

Bridging the gap

- Bring programmers **with less than 3 years** experience to the required expectation
- Build expertise of programmers with **more than 3 years** of experience but with limited exposure

An ideal statistical programmer will..

- Make an effort to have clear understanding of requirements
- Think about writing robust, data independent code
- Question specifications
- Provide input based on understanding of study design and data
- Spot problems and raise concerns in time
- Dot the **i**s and cross the **t**s

So sponsors need programme

- Strong Programming skills
- Clinical Domain knowledge
- Complex programming capabilities
- Communication skills

- Application of SAS techniques
- Programming methods for clinical study concepts

- Understanding of protocol, SAP and underlying assumptions

- Macro development
- Efficacy analysis
- Statistical tables and

- Communicating questions and issues effectively
- Study communication like analysis dataset specifications

Need a team
which has required
attributes
rather than required
experience

How

Directed training approach



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Our approach:

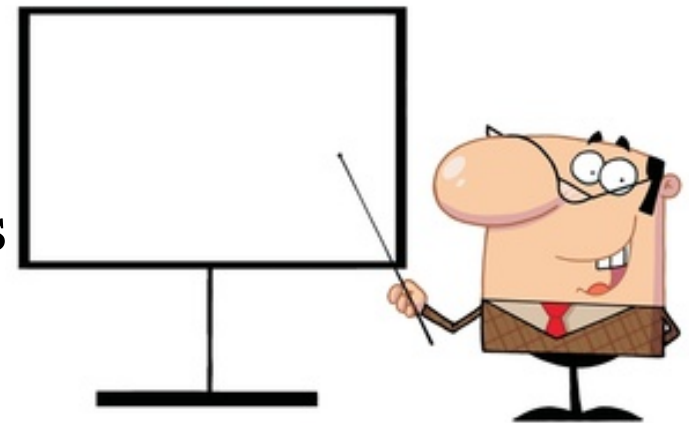
- Internship
- Mock assignments
- Internal and external training sessions
- Conferences
- Productivity tools
- Group discussions
- Dedicated mentors
- Mixed team composition and rotating teams

Mock Assignments

- Customized based on individual assessment
- Detailed review and feedback from supervisor
- Live project assignment based on progress
- Examples:
 - SDTM annotation and migration
 - Macro for lab CTC grading

Training

- By industry experts
 - Communication and presentation
 - Define.xml
- Internally designed based on project needs
 - CDISC SDTM
 - AE reporting
 - Survival Analysis
- Hands on exercises for all modules
- Solved in groups and discussed



Productivity Tools

- Automation team to develop macros and other tools
- Helps programmers build skills like defensive coding and writing efficient, modular code
- Open for all programmers



Group Discussions



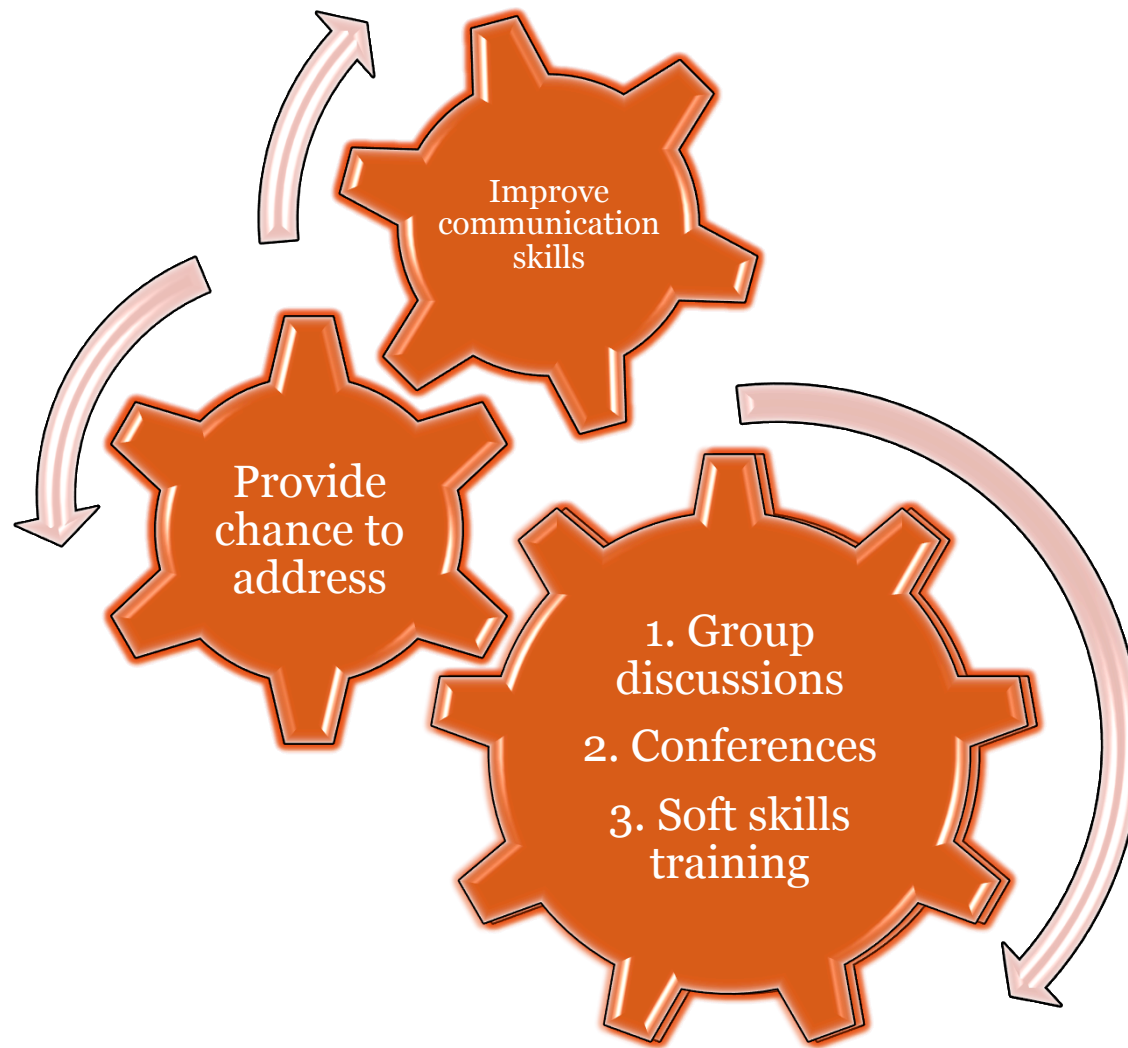
- Discuss clinical trial concepts
- Therapeutic area specifics
- Programming techniques
- Cross pollination of ideas and best practices across projects
- Small groups led by a mentor
- Participants research and present on topics

Technical Mentors

- Team and study leads
- Provide complete technical support
- Perform code and output review
- Develop and provide internal training
- Point of contact for client teams



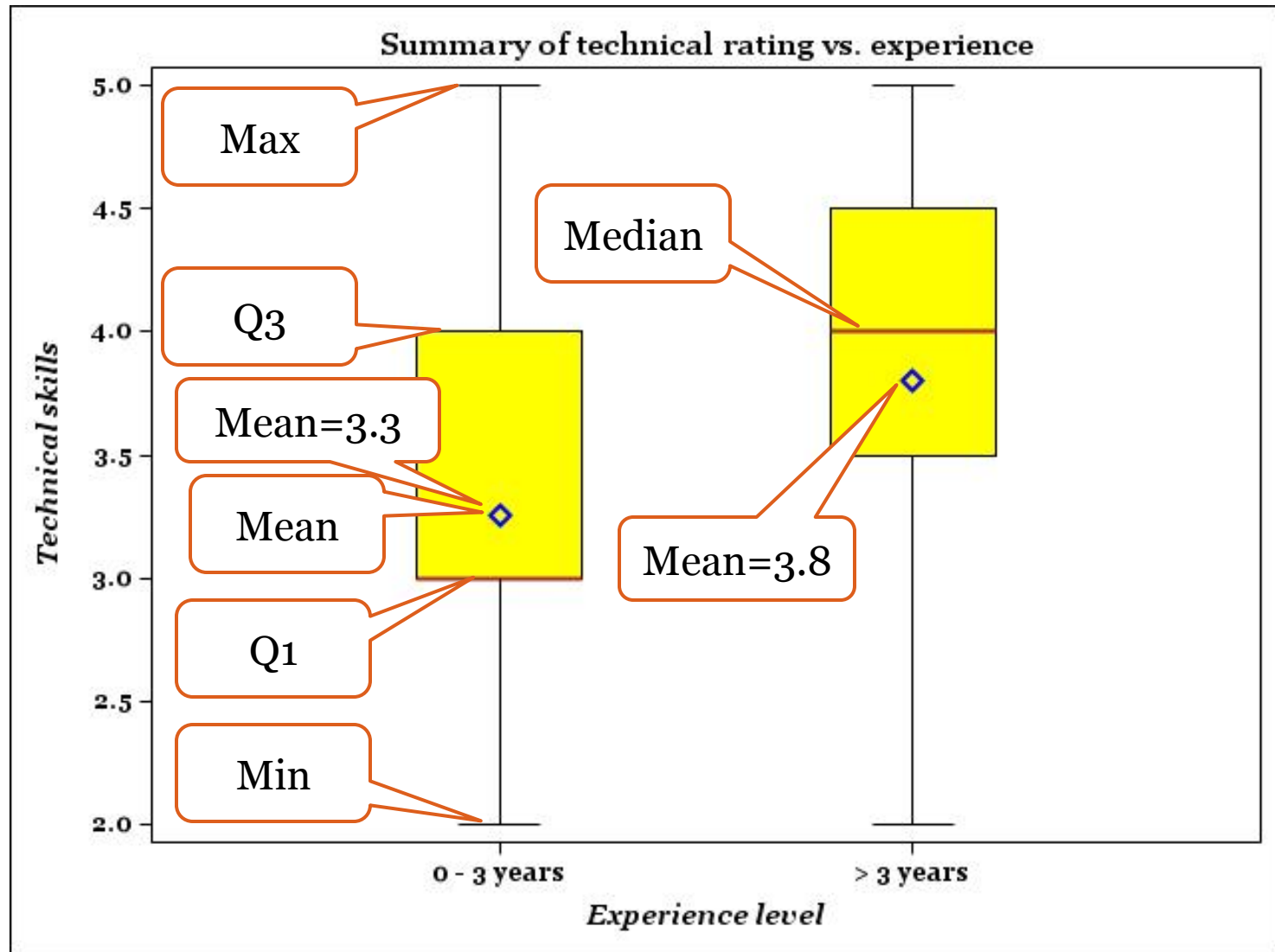
To summarize..



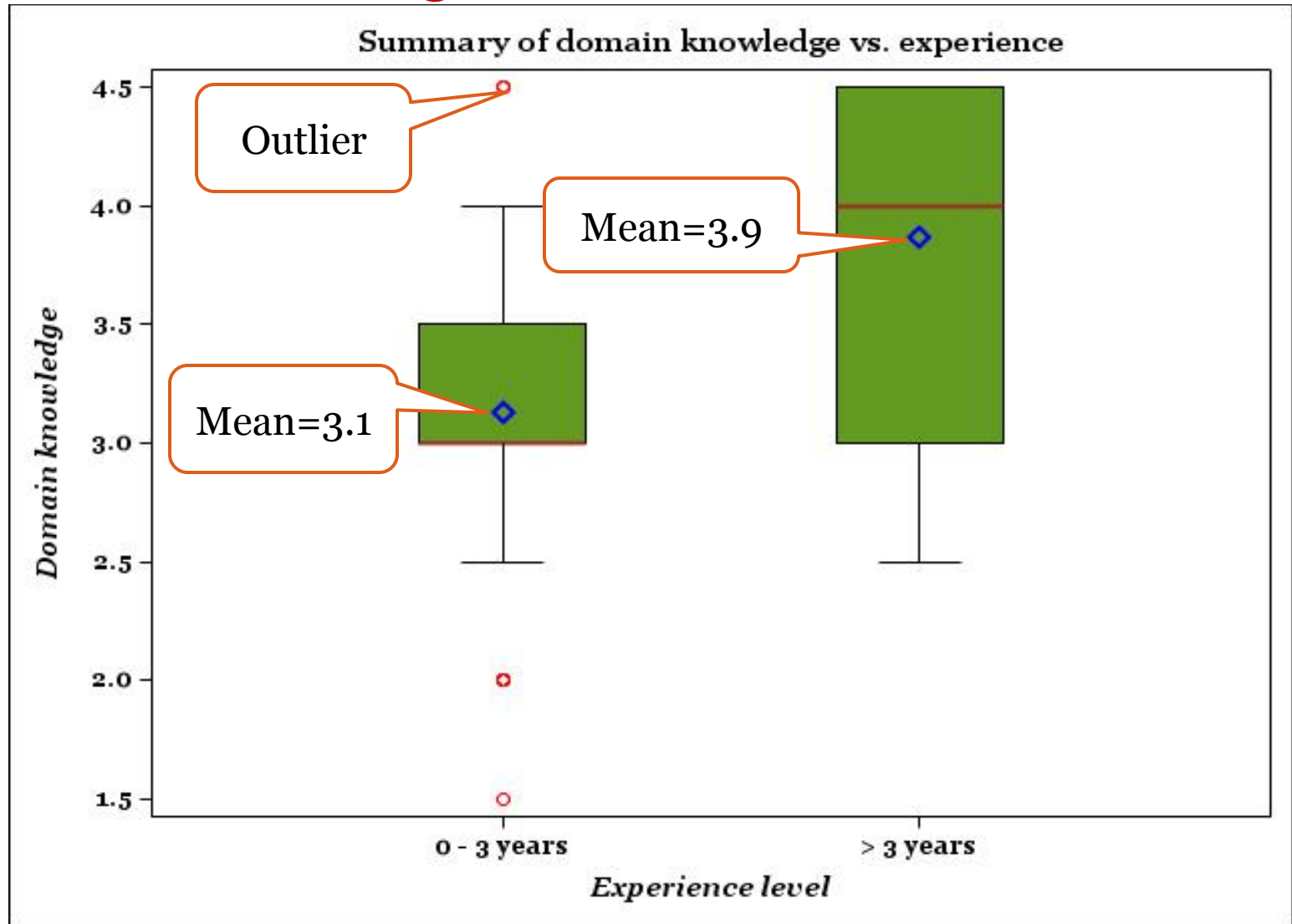
Is it effective?

- Collected ratings for programmers from line managers
- Reference point of 3-4 years of experience used for rating
- Consistent criteria irrespective of programmer's actual experience
- Sample set: around 70 programmers

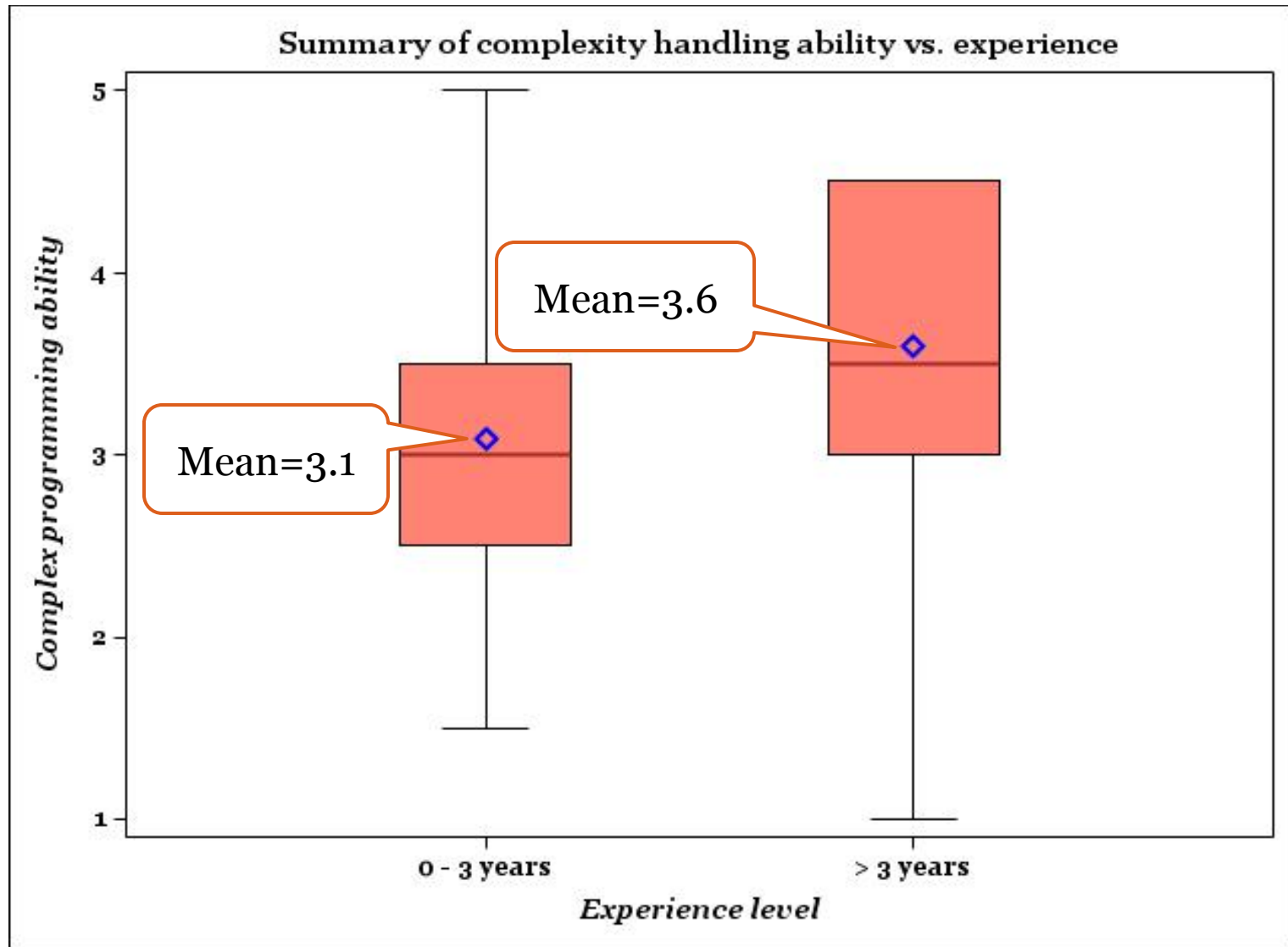
Technical skills



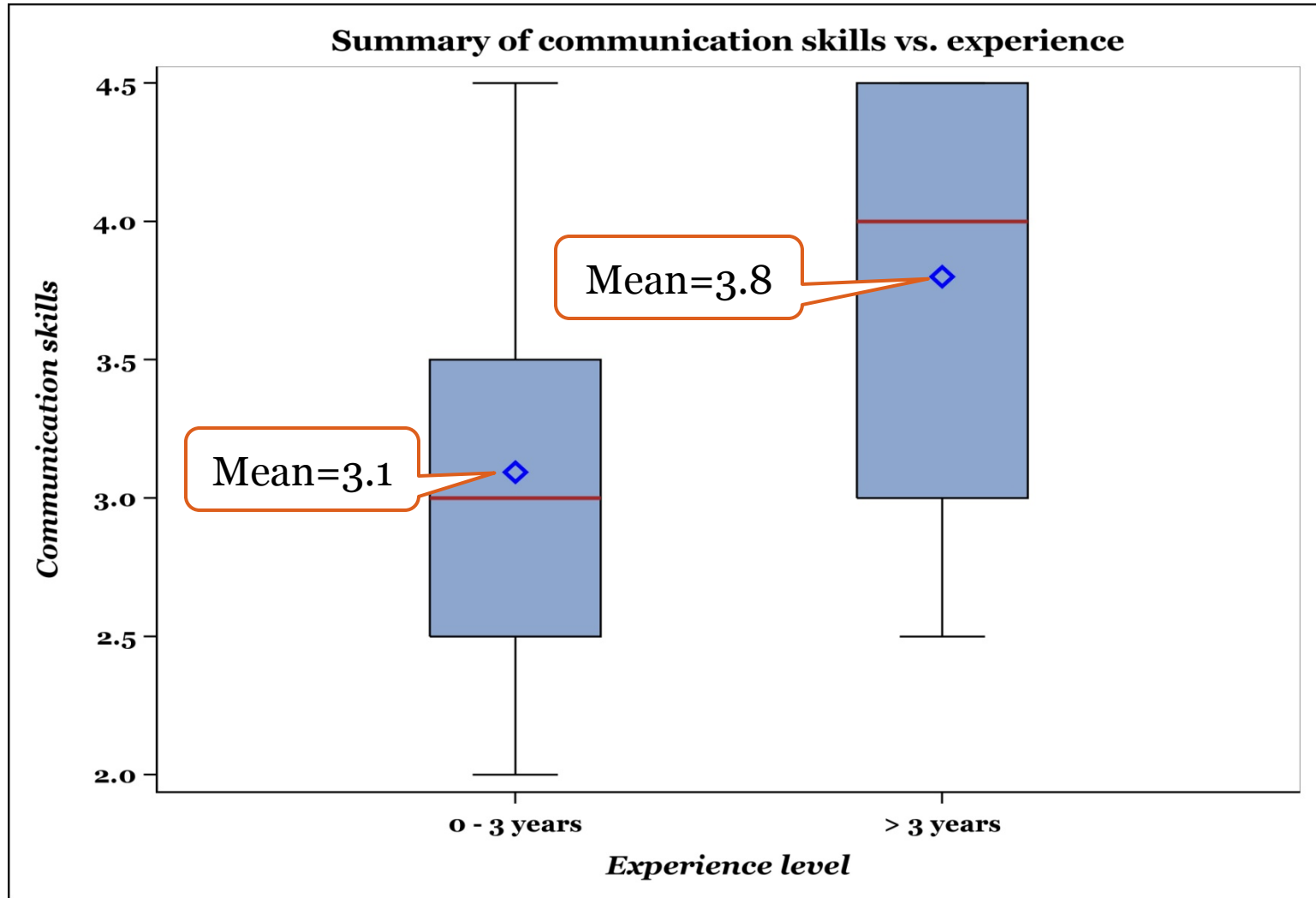
Domain knowledge



Complex programming



Communication skills



Results

	Average Rating	
	Level 1 N=43	Level 2 N=30
Technical	3.3	3.8
Domain	3.1	3.9
Complexity	3.1	3.6
Communication	3.1	3.8
Ratings: 1 = Unsatisfactory, 2 = Satisfactory, 3 = Good, 4 = Very Good, 5 = Excellent		
N = number of programmers with available ratings		
Level 1 : ≤ 3 years, Level 2: > 3 years		

Success story

Outcome:

1. Timely delivery with desired quality.
2. Both junior team members requested specifically for next assignment by client team.

Challenges

- External training expenses
- Significant time spent by experienced resources for:
 - Developing training material
 - Review
- Talented and experienced resource not always billable to clients
- Team size tends to be larger than ideal

Conclusion

Shortage of experienced and skilled resources

One of the best options for FSP: Comprehensive training process

Result:

Demonstrated that a well rounded

Happy Clients



Questions?