



I'M PRESENTING
AT THE
US CONNECT 2021

Virtual Event | June 14th-18th | Register at phuse.global/events_calendar

Hello!

I am Xiaohui Wang

With 20 years of project and people management experience; am passionate about improving team performance and efficiency; have lifelong curiosity for knowledge

Director, Statistical Programming group,
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Merck & Co., Inc., Kenilworth, NJ, USA



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How to Build Knowledge Capacity for A High-Performance Team



Xiaohui Wang,
Merck & Co., Inc, Rahway, NJ, USA



High Performing Team

Discipline

Empowers team to perform well at any circumstances, without cutting corners

Knowledge & Skill

Empowers the team with the capability to quickly comprehend and accomplish the tasks with high quality results and speed

Process & standards

Empowers the team to accomplish tasks efficiently, also systematically reduce error rate.

Collaboration

Accelerates the high performance team building in all areas.

Right Group Structure

Empowers the team members to develop their leadership and to be accountable for their deliverables





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Knowledge and Skills

Why it is so important

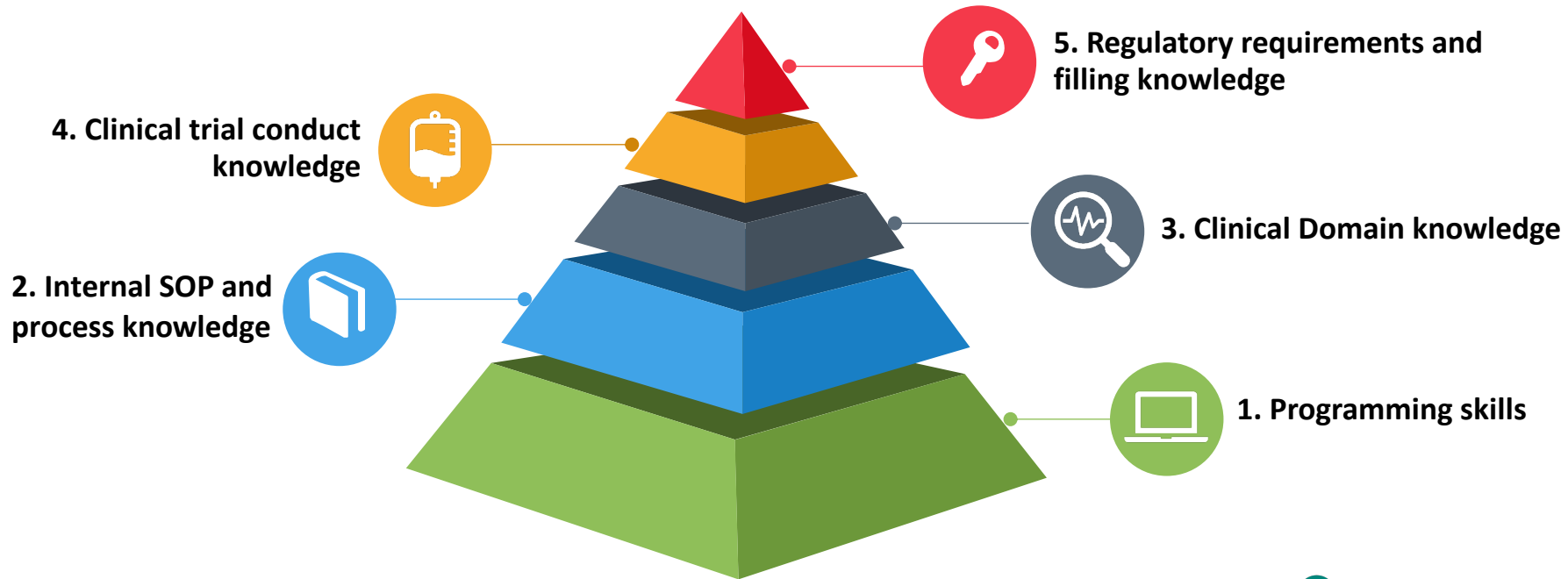
- Enable the team members to quickly comprehend tasks at hand;
- Enable the team members to accomplish the tasks with high quality results and speed;
- Enable individual team member perform independently in a global team

How to build team Knowledge

- Systematic training courses
- In need trainings
- Lessons learnt sharing
- Conference and researching on PhUSE white papers
- New technology exploration



5 Areas of knowledge building



☉ Purpose of SOPs



I. Programming skills

1. BASIC SAS SKILLS

Programmers are hired with at least basic programming skills

2. ADVANCED SAS TRAINING

SAS training courses;
third party training courses;
Internal training courses



4. NEW LANGUAGE LEARNING AND UTILIZATION

Encourage the learning of new languages to create tools to be prepared for the future.

3. KNOWLEDGE SHARING

Internal programming knowledge sharing;
External conference paper;
PhUSE white papers



II: Internal SOP and process knowledge

- Self-study the SOPs
- Bring questions to guided group discussion
- Going through SOP education and compliance checking cycle
- Timely education of Execution Resource or Business Guideline based on tasks.



III. Clinical Data Domain Knowledge

- Systematic knowledge of each clinical trial data collection domain
- From eCRF design → data collection guidance → edit check → SDTM → ADAM → Outputs
- CDISC standards
- MedDRA and WHO DD general knowledge

- Common Domains
 - Including Domains used cross studies of different TAs. Such as DM, MH, AE, CM, VS, LB, PK...
 - Common domain difference among TAs
- Therapeutical Areas/indication Domains
 - Large therapeutical areas such as oncology have multiple indications and each indication has multiple efficacy criteria
 - Oncology programmers should understand the details of these efficacy criteria definition, data collection, derivation and output presentation



IV. Clinical Trial Conduct Knowledge

- Concept of phase 1 to 4 clinical trials, corresponding study designs and their primary, secondary and exploratory endpoints.
- Clinical trial concepts related to the different phases of studies, especially, the blinding and unblinding concept.
- Reporting events of different phase studies.
- Study unblinding process.
- Full CSR and data packages.



V. Regulatory Requirements and Filling Knowledge

- Regulatory Compliance safety update annual report: IB, IND, DSUR, PSUR
- Knowledge of NDA submission:
 - Submission requirement of different agents, such as FDA, PMDA, EMA
 - Submission data requirement and standards
 - Efficacy and safety pooling strategy for integrated analysis including MedDRA and WHO DD leveling.
 - Real-Time Oncology Review
 - Preparation for Regulatory Agency request
 - Preparation for ODAC/ACM



Conclusion

With meticulous planning and execution, we can build programming, SOPs, clinical domain, clinical trial conduct, regulatory requirement and submission knowledge into a team's knowledge capacity.

The knowledge capacity of these five areas empowers the team members to quickly comprehend and accomplish the tasks with high quality results and speed, as well as transform the team into a high performing team.



Credits

Special thanks to all the people who made this presentation possible:

All the colleagues who have been working with me all these years building remarkable teams

All the managers and mentors who have been giving me inspirations and guidance



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Thanks!

Any questions ?

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