

Collaborative workings groups - why you should take part!

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ABSTRACT

Over the last decade, sharing knowledge and collaboration beyond company, industry, or regional borders evolved and became essential to the advancement of the field. Nonprofit working groups depend on volunteers motivated to work on a specific topic. When deciding to participate you will find it is much more than just a contribution but will advance your professional development weigh beyond your commitment. Success and fun are guaranteed as long as you are aware of the challenges you might face in a collaborative working group.

INTRODUCTION

Today we are constantly presented with globalization and continuous, ever faster evolution, like emerging technologies, exploding amounts of data, and increasingly complex regulations. These innovations have simultaneously created a greater need for collaboration and have facilitated that process across company, regional, and industry borders. Combined with the curiosity to learn from others and the motivation to improve processes, standards or techniques various collaborative working groups evolved. For example, PhUSE CSS facilitates voluntary working groups across companies and in collaboration with agencies and academics aiming to create commonly accepted deliverables and to foster innovation. The various CDISC teams, who are developing data standards are another example of global working groups run by volunteers. There are many more instances, locally and globally, where people identified a need for collaboration and initiated a non-profit working group in response. This paper will discuss how collaborative working groups operate, their main drivers and success factors, good volunteering practices, and various phases of contribution, as well as the benefits of involvement.

WORKING GROUP GOALS

There are various scenarios leading to the initiation of a working group. Basically, it is either a gap to be closed (e.g. the creation of the (c)SDRG and ADRG initiated through the FDA and realized through a PhUSE CSS working group), an enhancement to a process or standard (e.g. evolving Define-XML V2.0 from Define-XML V1.0 by the CDISC ADaM Metadata Subteam), a completely new idea for innovation (e.g. the exploration of RDF or blockchain technologies for application in the pharmaceutical environment through the PhUSE emerging technologies working groups), translating a regulatory requirement into practice (e.g. developing the PhUSE De-Identification Standard for SDTM triggered through EMA Policy 0070) or the demand for a platform to exchange know-how and experience. These platforms are also referred to as user groups, where people get together to share and work on implementation challenges.

Before starting a new collaboration effort, the common goal should be defined in the most clear and compelling way possible. Working groups' goals ultimately drive the motivation and engagement of the group. Goals can vary: putting together a white paper on the topic in question, developing or enhancing a standard, exploring an unknown subject, translating a regulatory requirement into practice and exchanging experience are all possible targets.

MOTIVATION CHECK

Answer the questions below to assess your motivation:

- Would you like to enhance your knowledge?
- Are you looking for challenges outside your day to day job?
- Are you interested in newly emerging topics which are not part of your core responsibilities?
- Do you like to hear other people's thoughts?
- Are you open to learning from others?
- Do you want to connect with people with similar interests outside of your working circle?
- Are you eager to contribute to the shaping of the industry for the future?
- Do you enjoy being part of a team and working together with others?
- Would you consider doing something of benefit for many on a voluntary and non-profit basis?
- Would you like to be part of an initiative across companies, countries, or even outside your industry?
- Are you keen to grow your network and get to know people?
- Would you like to gain feedback and acknowledgement outside of your day to day work?

If at least one of the answers above is "Yes", you should consider joining a collaborative working group.

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FINDING OUT ABOUT EXISTING WORKING GROUPS

Many volunteer-run, collaborative working groups exist throughout the industry, but there is no single source of information. Therefore, if interested in exchanging ideas and working with others on a specific topic, you can keep an eye out for these through resources in the internet. However, not all information is necessarily available in the internet, and some of it is hidden under different search keys. Approaching colleagues who appear well-connected within your organization for recommendations and subscribing to newsletters from the various societies are both wise approaches. The latter also gives the chance to join a working group as early as the initiation phase.

JOINING A WORKING GROUP

The way to join a working group might differ depending on the group itself or the society behind. This can vary from sending an informal e-mail to the working group lead to a formal application process. For example, if you consider joining a regional CDISC User Group, like the CDISC DACH UG, you would just need to add yourself to their e-mail distribution list on the respective CDISC Wiki page and immediately become a part of the knowledge exchange within this group. In case you want to volunteer for the PhUSE Board of Directors, which is the managing body of PhUSE, you will need to pass the formal application process once there are vacancies announced to the society. There are also application processes between these two extremes, which may have a prerequisite like a society membership for joining a working group. Any of these approaches are subject to change depending on the principles of a society, the status of the working group, the learnings made over time, etc. If seriously interested in the topic of the working group, the process should by no means prevent your application. It is more important to pass a thoughtful decision process beforehand.

GOOD VOLUNTEERING PRACTISE

The success of any working group depends heavily on the volunteers driving the effort. Therefore, careful considerations should be made before joining:

- Are the goals of the working group compelling?
- Is this the topic I am seriously interested in?
- How far has the group advanced towards its goals?
- Can I usually attend the regular meetings?
- Do I have time to contribute? How much spare time am I ready to invest?
- How many working groups can I be part of?
- What is the timeframe I am committing to?

Independent of knowledge and experience, no one, specifically newcomers, should be hesitant or afraid of signing up. There are numerous opportunities for valuable contribution for those who are not an expert on the topic or a long-time leader in the industry.

GOOD LEADERSHIP PRACTISE

Working groups cannot run without the respective leads. In many cases, the people initiating the effort also take over the leadership because they are passionate about the topic and ready to drive it forward. Nevertheless, some considerations should be made before taking on the responsibility:

- As the group depends on my investment and availability, can I commit to a regular involvement?
- Should a co-lead become involved? Who is available and a good supplement to my skills?
- Have the goals of the working group been clearly defined?

Besides being keen on the topic, working group leads need to be sensible regarding communication:

- Get back to volunteers who show interest, provide reasonable feedback and when possible, don't push anybody back.
- Motivate but remain patient.
- Provide room for everyone's contribution by taking different personal strengths and experience into account.
- Stay focused.
- Set realistic goals and adopt intermediate steps throughout the process as needed.
- Acknowledge your collaborators' contributions.
- Consider communication to the working group's larger organization, like PSI, CDISC or PhUSE and the public about the working group's progress and achievements at the right time.

TAKING PART IN A WORKING GROUP

As soon as you are part of the team, you will experience how the specific working group operates and how you can best contribute.

ORGANIZATIONAL STRUCTURE

Collaborative working groups bring together insights from different perspectives and specialized knowledge. Even if mainly self-managed a flat organizational structure is required that allows for successful team work:

- Lead and Co-Lead(s),
Working group leads are mainly responsible for targeting the team towards the goal of the working group. The role is like managing an internal team within a company but without disciplinary responsibility. Mainly, it is about motivation and focus.

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- Team members,
Team members contribute to the goal of the working group, ideally in areas that match their personal strengths. It should be kept in mind, that the pace of voluntary work might vary based on the demand of each member's day to day responsibilities.
- (Organizers/facilitators)
Organizers, if available, support the team by scheduling meetings, providing shared platforms to store information, and preparing minutes.

WORKING GROUP MEETINGS

Regular meetings are the centerpiece of all working groups as they provide the platform for an open and collaborative exchange between all team members. In many cases, these are telephone calls or web meetings. Some working groups have the chance to meet in person from time to time. Face-to-face meetings build a great deal of team morale and trust. It is much more of a challenge to create and obtain the collaborative atmosphere without offline interactions. Adherence to some core principles, particularly regarding respect towards all other team members and their voluntary time, is key to overcoming distance in web meetings.

Core business rules, for both working group meetings as well as contribution during the intervening period, help keep the team going and motivated. It is necessary to keep in mind, that it is voluntary work and the commitment is driven by interest only. Thoughtfulness and patience are key to all volunteer initiatives.

GOOD MEETING PRACTISE

Before a meeting:

- As a lead:
 - o In a global setting, consider time zones and national holidays when scheduling meetings
 - o Find the right frequency.
 - o Set up an agenda ahead of a meeting to allow for preparation.
 - o Identify a minutes taker.
 - o Let your co-leads know as early as possible, if they need to step in and lead the meeting. In any case, don't let people dial in and recognizing only at that time of the meeting that it won't take place.
- As a team member:
 - o Let the leads know in case you cannot join a meeting.
 - o Bring topics to the agenda ahead of the meeting.

During a meeting:

- Try to arrive on time.
- Expect technical challenges.
- Mute yourself while not talking.
- Not everybody is native in English and cultural difference might add. Make the effort and try to understand everyone. Speak clearly and use concise language.
- Communication skills and professional experience differ. Take every statement and question seriously and without prejudice. Everybody should feel encouraged to speak up.
- Background knowledge about the topic in question is usually not evenly distributed within the team. That is one of the objectives of the working group to bring everybody forward.
- Engage yourself. Don't be shy but leave room for other people's thoughts as well. Be self-aware and recognize how much you are talking in relation to other group members. Be comfortable with natural pauses, these give members who are new, non-native English speakers, or simply on the shy side, time to formulate their thoughts before contributing.
- Don't distract yourself by working on other tasks during the meeting.
- When new to the group, take some time to listen first. Also use resources to familiarize with the working group to avoid re-discussion, even if this is just reading minutes from previous meetings or speaking informally with another member of the group. Nonetheless, new / late joiners might bring up topics, which were discussed before. Be patient, as re-discussion might also trigger new ideas or challenge decisions.
- Being part of a working group just to listen is fine as long as this is limited to an introductory phase. It has to be kept in mind, that working groups cannot consist of listeners only but rely on the commitment of many.
- Take on active roles as you can realistically commit to. This does not mean, you need to wait until an opportunity comes up. Specifically, if everyone has set roles by the time you join but you proactively identify an area that you are interested in, ask how you can help or be involved even if the opportunity wasn't explicitly presented.
- Don't expect the work to be evenly distributed. Member commitment usually varies and might change over time depending on the demands of their main position and interest or aptitude for specific tasks.

After a meeting:

- Review the minutes and provide feedback. Minutes are key to make sure everybody has the same understanding and can follow the group's progress.
- Make sure action items are clearly defined and addressed.
- Don't be hesitant to communicate to other team members outside of formal meetings.

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GOOD CONTRIBUTION PRACTISE

Achieving goals usually requires follow-up and outside work between the meetings shared amongst the team. The respective commitment of team members is therefore key to the achievement of intermediate and final goals.

There is a broad variety of possible assignments ranging from

- Proposing topics for consideration and discussion.
- Putting together meeting minutes.
- Reviewing draft documents in terms of completeness, comprehensibility, correctness, or just grammar and spelling.
- Doing research and gathering information for the group to work with.
- Connecting with others, in- and outside the working group to find out about specific sub-topics.
- Elaborating on a topic for further discussion within the group.
- Working on deliverables, e.g. putting together a guidance document or template for public use.
- Putting together material for presentations.
- Getting involved in a sub-team. Some tasks might merit the creation of sub-teams. Small groups can often achieve results faster than a large team and thus contribute efficiently to the overall team success.

Be aware that being proactive or getting back with completed tasks will motivate others to do the same.

Nevertheless, it is important to only commit as time allows.

WORKING GROUP ROUTINE

In some respects, voluntary groups function similarly to company internal project teams. There is a lot of enthusiasm in the beginning before realizing hurdles and setbacks. Some team members might step back due to loss of motivation. Others might not be able to regularly join TCs or lose track of progress and need to be brought back to speed. Respect and patience with others will keep the team going, in many cases at a slower pace than in the daily responsibilities. Overcoming these challenges by not giving up, contributing while others don't have time but keeping them in the loop while awaiting them to do the same at another point in time is key to success. Therefore, being transparent and sharing professional or personal constraints with the team supports team spirit and maintains motivation.

WINNING WITH A WORKING GROUP

There are many factors influencing why and how you will benefit from taking part in an initiative driven by volunteers.

WORKING GROUP ACHIEVEMENTS

Working together with others as a team is inspiring, creates new ideas, builds trust and, if not driven by company interests, has shown to be effective in terms of achieving commonly accepted results. Over the last years, various voluntary teams managed to impress the industry by publishing their working group results for implementation in the industry. Achieving overall or intermediate targets is already rewarding as such and everybody who contributed can rightly be proud to be listed as working group contributor:

Imagine having taken part in the working group which

- developed the GPP Guidance Document V1.0, which was referenced in FDA presentations.
- introduced an across-company defined and globally acceptable set of KPIs in clinical data science.
- translated new regulations into implementation standards, e.g. for EMA 0070.
- improved standards from implementation feedback, e.g. CDISC ADaM 2.0.
- introduced standard documents facilitating regulatory review during the drug approval process, e.g. (c)SDRG, ADRG, SDSP.

When working group members come together from organizations with differing goals and reach conclusions and recommendations such as those listed above, the collaboration speaks volumes and the result is more likely to be considered and valued by the industry and authorities.

PERSONAL ACHIEVEMENTS

As a member of an initiative, you will get in touch with people outside your company sharing the same interest. New relationships will be built and you will grow your network. Many people will also get to know you as soon as the working group achievements get published and you will be recognized as a contributor who advances the industry. But already at the time of taking part in a collaborative initiative, there are personal learnings and rewards to be expected. Firstly, it is about expanding the knowledge about the topic in question. Regardless of the level of expertise at which people join the group, additional knowledge will be gained throughout the collaborative effort. Besides, there is the room for personal development. Everybody can engage without restrictions and benefit from working with other volunteers. Learnings range from gaining experience in working with a global virtual team, overcoming linguistic and cultural challenges, understanding everyone's main driver for contribution, acting professionally in a diverse team without knowing people's background, finding the own role, contributing with value and being accepted and acknowledged by the rest of team as a valuable contributor.

It has to be taken into account that reward might only be seen after quite some time of contribution. Depending on the field of engagement, it can take time until you will be recognized as an expert and acknowledged as such. Working group leads are recognized more easily by the public as they are usually sharing progress and results. But also, as an engaged team member an acknowledged expert level can be achieved by continuous and professional

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contribution. Imagine, supporting the development of a standard over some years and at some point, becoming the proposed expert to present the concept to a regulatory authority.

CONCLUSION

Working in groups creates motivation and self-management. In voluntary teams, where the decision to take part is with the individual and driven by interest, the conditions are ideal to turn team spirit and enthusiasm into achievements and acknowledgement. Possible commitment of the volunteers in addition to their day-to-day obligations drive the pace. Thus, staying patient without losing energy is a core challenge to overcome. Collaborative working groups bring together insights from different perspectives and specialized knowledge. Over the last years, various voluntary working groups advanced the field and created value for the industry as well as for the regulatory agencies and some even extend into academia. Due to the success and recognition, the number of voluntary initiatives evolved, and a broad variety of topics now gets addressed across borders of companies. Besides rewarding accomplishments of the team, individuals benefit in their career development by gaining expert knowledge and by training their soft skills or even developing leadership competencies. An additional benefit of participation is the valuable opportunity to connect across borders. It is thus not the question if to take part in a collaborative working group but to individually choose the right one.

REFERENCES (HEADER 1)

Information on some exemplary working groups can be found at:

<https://www.phuse.eu/phuse-working-groups><https://wiki.cdisc.org/display/CDISCTC/CDISC+Team+Charters+Home>
<https://wiki.cdisc.org/display/PUB/CDISC+User+Networks>
<https://www.psiweb.org/sigs-special-interest-groups/sigs>
https://www.efspi.org/EFSPI/About_EFSPI/Working_Groups.aspx

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