



Society for Clinical Data Management  
DATA DRIVEN

# Data Basics

To advance excellence  
in the management  
of clinical data

A PUBLICATION SUPPORTED BY AND FOR THE MEMBERS OF THE SOCIETY FOR CLINICAL DATA MANAGEMENT, INC.

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## Letter from the Chair

Ralph J. Russo

This issue of data basics focuses on Virtual Teams/ Project Management.

SCDM itself is a virtual organization. For example:

- Our Board of Trustees operates in virtual mode with our management staff in Milwaukee on a daily basis. Each of our Board Members is involved in Board-level task forces covering various topics. They are required to keep in contact with other task force members, external partners, and our staff in Milwaukee at all times.
- In between our face-to-face Board meeting, the business of our Society is kept running through teleconferences and e-mail exchanges between our Finance Committee, Executive Committee and Staff.
- SCDM's committees and task forces ac-

complish all of their incredible work in virtual teams. Marketing, Webinars, Good Clinical Data Management Practices chapters, and all other content are developed virtually through our strong and dedicated network of volunteers.

Most data management professionals work on virtual teams these days as well. Technology allows anyone to be connected to their work and remote colleagues from just about anywhere. Certainly there are challenges in managing these virtual arrangements. I hope you'll find the articles assembled in this Summer issue a valuable reference to helping your organization succeed using virtual teams. Print a copy and bring it to the beach for a little light reading! ■

## Managing Virtual Teams

Donna Gugger, Associate Director, Clinical Data Management at United BioSource Corporation; Lisa Hanson, Project Manager at United BioSource Corporation



### Evolution of Teams

In today's digital world, information and communication technology advances have broken down boundaries within and between organizations. The global economy, mergers and acquisitions environment and decreased travel budgets have caused organizational teams to be spread across the globe. No longer is it

the norm for study teams to be co-located and to interact through face to face communications.

Virtual teams have become the new norm. A virtual team (also known as a geographically dispersed team) can be defined as a project team functioning in different locations. This group of individuals works across time, space and organizational boundaries, strengthened by the links of communication technology and a common purpose.

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## Managing Virtual Teams

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Traditional methods of managing teams can no longer be used to ensure the success of a virtual team. Those in leadership positions must understand the complexities involved in working with virtual teams. We can no longer look towards a single leader as has been done in the past; instead, we must lead collectively, to ensure all resources, separated by time, space and cultural diversity, feel part of a cohesive team.

### ***Opportunities and Challenges of Virtual Teams***

Many of the challenges of a virtual team can also be considered opportunities. One benefit of a virtual team is the opportunity to utilize the best resources available. Talent for your team can be obtained regardless of physical location, providing many opportunities for career development. Resource management can also be challenging, as it is more difficult to ensure team member accountability and distance complicates the management of training and performance.

Another opportunity or challenge of a virtual team is the cultural diversity of the team members. The challenges of a culturally diverse team are more pronounced as communication gaps can result in a misunderstanding of priorities, team objectives or perceptions. Cultural diversity is clearly an opportunity for the team when it is considered that team members provide different approaches to problem solving or are fluent in different languages, which can prove to be beneficial, for example, with site training, query resolution or translations.

### ***Steps for Building and Managing Virtual Teams***

Building a strong foundation is essential to the success of a virtual team. Team expectations, purpose and values must be clearly defined. Roles and responsibilities of team members should be documented. The project team's and key shareholder's buy-in can be secured by permitting them to provide input and feedback.

Beginning with a clearly defined scope of work, resources can be assigned to meet study needs based on an assessment of individual skills. Tasks are allocated based on the best fit. When there is not a clear alignment of tasks, it can provide opportunities for career growth when team members take on new tasks which improve their skill set.

It is critical that the team leader and members learn as much as possible about the working cultures of the members who will comprise the team. There are a number of cultural tendencies that should be clearly understood as a team is forming and as new members join the team. These include characteristics of implicit versus explicit communication, individualistic versus team mentality and uncertainty avoidance.

There are certain types of training that can be considered unique to virtual team members. This training includes utilization of technology tools, effective collaboration in workgroups and techniques and best practices in conducting a virtual meeting.

Effective communication is considered to be one of the most critical factors in determining the success of a virtual team. There are a number of strategies that a team leader and team members alike can utilize within a virtual team setting.

A communication plan is an effective tool for providing the team with communication guidelines and etiquette. It can define the type of communication that is appropriate for a situation (e.g. email versus phone call), an expected turn-around time to respond to messages, an escalation process for problem resolution and a list of contacts for the project, including roles and responsibilities for each team member.

There are also a wide variety of technological tools available to allow virtual teams to com-

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## Managing Virtual Teams

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municate effectively and work seamlessly. Some of the tools available are listed below:

- Live Meeting (Microsoft Office product) [www.livemeeting.com](http://www.livemeeting.com)
- WebEx (Cisco product) [www.webex.com](http://www.webex.com)
- GoToMeeting (Citrix) [www.GoToMeeting.com](http://www.GoToMeeting.com)
- Teleconference, Videoconference
- Skype
- Chat Room

A shared document repository such as Microsoft Windows SharePoint or SiteScope Forum is essential to ensure that all team members have the most up-to-date team documents and critical communications readily available to them. Below is an example of a SharePoint web site:

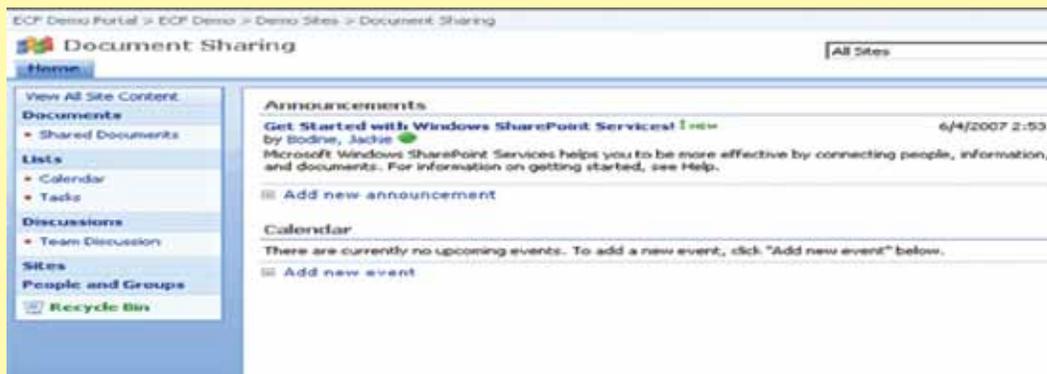


Figure 1. Example of a Shared Document Repository

Rules of engagement should be considered to ensure that consideration is provided to team members in a culturally diverse group. Active listening, introductions, speaking clearly, avoiding humor and irony are tactics that can be used to ensure that all individuals feel comfortable being engaged in team communications.

Strong leadership is critical to the success of building and maintaining a successful virtual team. Leaders will need to overcome the challenges of building trust and relationships when face-to-face encounters are rare, if at all. In order to foster strong team dynamics, leaders must clearly define expectations, set ground rules and ensure that team members are provided with rewards and recognition for their contributions.

In a global setting, leadership support will be necessary to co-lead the team considering teams are working during different work hours and time zones. Leaders sharing the same common values can encourage team interaction based on the ability to provide support and communication to distant teams. Leaders with close proximity can ensure that goals are clear, priorities are understood, team members are accountable and workloads are managed at local sites. When teams share the same values and have strong leadership, trusted relationships prevail. Team members in distant locations can feel that they are not isolated and that their accomplishments will be known.

### Best Practices

There are a number of best practices to consider for building virtual teams. It is critical to have a Kick-Off Meeting or Orientation Meeting, preferably face-to-face. It is important to schedule regular team meetings even if there are limited topics to discuss. Bringing the team together will help ensure they feel connected with the team's goals and objectives. Having clearly written documents such as a Project Plan, Contact List, Decision Logs, Action Items,

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# Telecommuting: Challenges and Benefits

Shannon Labout CCDM, Director of Education CDISC



People from a certain generation may remember a cartoon from 1962-63 called the Jetsons, which portrayed the daily life of people in the future. The cartoon included jet powered cars, robotic maids and futuristic homes where meals were prepared effortlessly and cleaned up instantly. Interestingly enough, even with jet powered cars and

instant meals, the cartoon still portrayed dad grabbing his briefcase and getting into the jet car every morning for the commute to his job where he pressed one button and then put his feet up for the rest of the day. From our perspective in 2010 we all realize George Jetson probably had a job perfectly suited to telecommuting, but in fact the idea of working remotely was so foreign to our national consciousness in the early 1960's that this idea may not have even entered the car-

toonist's imagination at that time.

Thirty or so years ago, most managers would not have considered remote work arrangements to be appropriate for their organizations partly because the equipment required to operate a business was too large and expensive to de-centralize it, and partly because a popular style of management at that time was based on the prevailing theory that workers would not be productive unless they were constantly watched and supervised. In the past couple of decades more progressive management theories have been introduced, and computers and internet technologies have opened up opportunities for us to work from virtually anywhere in the world with anyone else anywhere in the world; and yet in many cases, the management style in our organizations has not changed from the 1960's view that workers must be on site and in sight at all times. You may ask, though, why is this important as long as the work is done?

Sociologists often group populations in the Western world by generations to explain common attitudes and trends. We have the Silent Generation, the Baby Boomers, Generation X and so forth. While we are all individuals and have our own view of what makes a good life, there do seem to be some common generational attitudes and so it is important for hiring organizations to understand the generational differences as the current workforce matures and younger generations become the majority in the professional world. For example, while Baby Boomers and older generations might have received job satisfaction based mainly on the size of their paycheck or on the length of their employment with the same organization, younger generations are more likely to seek out employment situations that contribute positively to their quality of life and this may be the single most important factor when they are deciding between one job

## Managing Virtual Teams

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Data Management Plan and Study Timelines will help the team stay current on upcoming milestones, outstanding items critical for resolution and critical path issues.

### Conclusion

In summary, virtual teams are rapidly becoming the norm for team composition in most organizations. The keys for virtual teams to be successful in meeting their goals include building a strong foundation during team formation, ensuring the right resources as assigned and trained; and providing strong leadership on an ongoing basis to ensure team members are well informed, connected with other team members through appropriate technology tools and committed to the team's goals and objectives. ■

### References

- Duarte DL, Snyder NT. *Mastering Virtual Teams*. 3rd edition.
- Kahai S. *Implicit Communication and Culture: What it Means for Leading Virtual Teams*. [www.leadingvirtually.com](http://www.leadingvirtually.com)
- Kimball L. *Managing Virtual Teams*. [www.groupjaz.com](http://www.groupjaz.com)
- Raines L. *Managing Virtual Teams Takes Extra Care*. [www.ajc.com](http://www.ajc.com)
- Rasmussen J. *The Five C's of Managing Virtual Teams*. [www.rasmussencentral.com](http://www.rasmussencentral.com)
- [http://en.wikibooks.org/wiki/Managing\\_Groups\\_and\\_Teams](http://en.wikibooks.org/wiki/Managing_Groups_and_Teams)
- <http://en.wikipedia.org>
- Noble S. *President 3D Learning, LLC. Starting Up a Virtual Team*.
- Joinson C. *Managing Virtual Teams: Keeping Members on the same page without being in the same place poses challenges for managers*. *HR Magazine*, June 2002.

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## Telecommuting: Challenges and Benefits

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offer and another. No matter what the average age of their employees is, employers who are concerned about reducing hiring, relocation and training costs will certainly benefit from implementing policies that not only provide financial stability, but which also contribute to the quality of life for all of their employees.

### ***Benefits and Challenges for the Employee***

So how does telecommuting contribute to an employee's quality of life? There are many ways! The telecommuting employee may have a more flexible work schedule that fits in with a current family situation and allows a better work/life balance. This in turn can reduce stress and contribute to better health, more energy to put into job activities and a more motivated employee in general. Telecommuting also reduces the employee's costs for driving or other commuting expenses, and for clothing purchases and cleaning. The employee who telecommutes also does not have to worry about coming into contact with contagiously ill colleagues in the office. Often a remote work location offers reduced distractions and interruptions, so employees can be more productive during the workday thereby also contributing to increased job satisfaction. Having the flexibility for one family member to keep a job when another family member's situation requires relocation can also be a great benefit to the employee. Simply feeling trusted to work from a remote location will cause many employees to respond by working extra hard to prove they are worthy of that trust.

There are challenges to working remotely, though, especially from a home office. The person who is successful at this will need above-average time management skills and the ability to set reasonable work hours and boundaries between home and work life. The reduced face-to-face time with colleagues can be also difficult for certain personality types who need interaction with other people to stimulate their cre-

ativity. Some people may feel as though being out of the office environment limits their career advancement because they are out of sight and possibly out of mind of the boss. The telecommuter may also have to be more self sufficient in handling problems with computer equipment, software packages and related tools. These are limitations that the telecommuting organization should be aware of so steps can be taken to mitigate the potentially negative effects of telecommuting.

### ***Benefits and Challenges for the Employer***

Telecommuting also has many benefits and some challenges for the employer. The employer benefits from all of the things that are positive for the employee by having more motivated, productive employees who are likely to stay with the organization for a longer period of time. This can lead to the organization being viewed as an employer of choice and having better overall employee retention. Employee retention has a positive financial benefit by reducing hiring, training and relocation costs. Other positive aspects of employee retention include the preservation of knowledge and expertise that exists in employees who have a history within the organization. Many costs for the employer can also be reduced or eliminated through telecommuting programs, such as real estate, office equipment, furniture and utilities, and facilities management costs. Having an established telecommuting policy also sends a message to the community that the organization is socially responsible. Telecommuting reduces commuter pollution, energy use and commuting-related accidents and traffic congestion. The organization that promotes telecommuting is also contributing to public health by not exposing employees to contagions in the office (e.g., during flu season). All of these positive health effects in turn potentially reduce the employers' costs for providing health care to employees and their families.

The challenges that exist are few compared to the benefits, but they include the need for an equitable policy and robust documentation in the application of the policy. There are also management challenges in selecting the appropriate positions and people for telecommuting. Managers and colleagues in a virtual organization have an increased need for excellent written and verbal communication skills since most of their communications will occur through electronic media. Telecommuting may also require a strong data protection plan to preserve the privacy, integrity and security of proprietary information housed in computerized systems.

There are clearly both benefits and challenges for employer and employee in telecommuting, and every organization will need to determine what makes sense for them and how best to implement a remote work policy. In most cases, though, the benefits far outweigh the challenges for both employer and employee and a carefully planned and implemented telecommuting policy has the potential to produce a healthier more productive organization. ■

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## True Partnerships

Nelson Lee at the Society for Clinical Data Management (SCDM) reviews some lessons learnt from building a functional service provider partnership. Published in ICT May 2010; reprinted with permission.



The traditional full-service CRO model for clinical data management (CDM) is evolving into something different – a functional service provider (FSP) model. Instead of outsourcing the entire suite of CDM tasks, sponsor companies only outsource selected CDM activities, maximising operational and budgetary efficiency. While this model has become a key player in CDM resourcing strategy, it is a complex partnership and requires careful planning and examination prior to implementation.

A successful FSP partnership is critical to CDM operation for pharmaceutical and biotech companies. While a well-planned FSP implementation is a good starting point, a long-term strategy for building and maintaining an FSP partnership is equally important. When an FSP is selected, it is merely the beginning of the partnership journey. It takes numerous considerations and planning to ensure a successful implementation. Furthermore, many of the im-

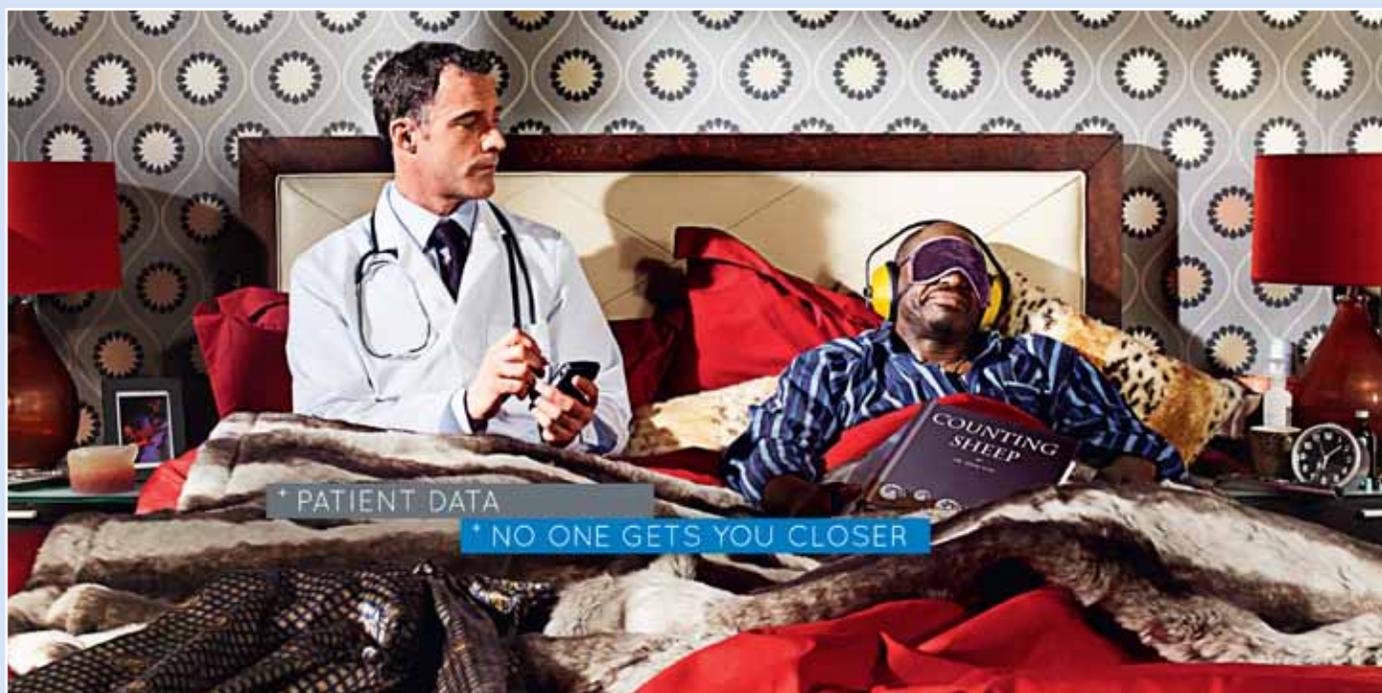
plementation steps are critical to – and have a profound impact on – the partnership. This article will share some key lessons learned in FSP implementation and maintaining FSP partnership from a sponsor's perspective.

### Work Order

It is important to establish a process to outsource works to FSPs. A simple and effective way is to use a work order that states the tasks the FSP will support. The tasks should be specific enough that they do not leave room for different interpretations. Consider the task edit check programming. If this is all that is listed, the FSP could interpret the requested service with any level of details. Are unit testing and quality assurance activities part of this task? Who is responsible? Is the FSP responsible for all types of edit checks?

The key lesson here is to ensure a clear understanding of the full scope of any tasks the FSP is responsible for. This leads to the importance of setting clear expectations and understanding of common terminology and processes.

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## True Partnerships

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Edit check programming can be broad. As electronic data capture (EDC) gains a foothold in CDM, it is imperative to understand exactly what edit check programming means.

There are different types of edit checks. The most common type is discrepancy checks. For example, when checking for a current visit date, the date must be after the informed consent date. Some checks are programmed to ensure certain data flow and form logic. If 'female' is entered in the gender field on the demography form, a logic check will be engaged and make the serum pregnancy form available for entry.

EDC systems have multiple built-in, or system, checks that do not require programming. These checks can be easily implemented by merely turning on built-in features.

Checks that require a response or ensure conformant data are common system checks.

While a work order can easily be prepared by a clinical data manager, there must be a control point on the outflow of work orders to ensure FSP support is used properly by staff. It is advisable to have a point person internally who can authorize the work order. Likewise, a point person on the FSP side should be designated to receive and authorize the work order. If there is no agreement, the FSP must not start any work, even if a work order was received. Only authorized and agreed tasks between the sponsor company and the FSP should be performed.

### *The Terminology Trap*

Setting clear expectations is critical. There is jargon in the CDM community that means different things in different companies. The keys are to avoid making assumptions and to ensure the FSP has the same knowledge of the CDM processes employed internally.

Some companies include unit testing and quality assurance as part of the edit programming practice, some include quality assurance procedures in user acceptance testing. Likewise, some companies require the programmer who programs the checks to perform unit testing, some require a different programmer to perform the task.

To avoid confusion, the FSP needs to be educated and trained on the same practice. Specific requirements, including study-built conventions, must be transparent and clearly communicated to the FSP so they can meet the expectations of the sponsor. If unit testing requires two sets of testing data (one to trigger the checks, one to pass them), this requirement must be communicated to the FSP upfront.

### *Knowledge and Experience*

Let us look at another scenario, where an FSP study requested edit check programming support. The FSP assigned an ICT I [www.samedanltd.com](http://www.samedanltd.com) experienced clinical database programmer to lead a team of three other programmers. When the sponsor conducted an internal review of the FSP deliverables, they found an unusually high number of programming errors. Further investigation identified one of the programmers had four times more errors than the rest of the team.

The FSP revealed that this programmer was a new addition to the pool of candidates in the FSP model and was a replacement for a senior programmer. Though this new programmer had all the proper training documents, he had no experience performing programming work in the EDC system employed by the sponsor.

FSP staff turnover is unavoidable and is uncontrollable by the sponsor company. The minimum requirements to carry out CDM tasks by job title must be set and shared with the FSP. The FSP is expected to use the same criteria to assign a pool of qualified candidates because the sponsor is expecting turnkey operations in the FSP model. Outsourced CDM activities are not meant to be a training opportunity for the FSP staff. If the sponsor requires an internal employee to have certain knowledge and experience to handle a specific task, the same set of criteria must apply to FSP staff doing the same task. Failure to meet these expectations will have a ripple effect and can result in quality concerns or missed timelines.

Let's go back to the above scenario of FSP programmer errors. The FSP took immediate action and implemented an extra step to review all work done by the new programmer. Though the team was able to meet timelines and quality expectations, the extra review and necessary corrections generated a higher number of reported work hours, resulting in higher billable hours by the FSP.

The sponsor company now wonders why they are stuck with the extra cost. This damages the trust and confidence in working with the FSP (and in particular the programmer) – and its reputation. The cost-benefit, quality expectations and timelines must not be negatively affected by less trained or inexperienced staff. These factors are key to successful CDM deliverables and to the successful FSP partnership.

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## True Partnerships

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### Staff Satisfaction

It is no secret that there is a cost-benefit component in using FSPs. And it is nearly inevitable that internal CDM staff sense a threat in their job security. Employees frequently become concerned that they will lose skills as tasks are outsourced. This concern needs to be addressed promptly by CDM management of the sponsor company, enabling full cooperation and acceptance, or at least minimised resistance, from internal staff. Management must communicate the rationale and benefits, according to the unmet medical needs, to the trial, to the company and to staff, of adopting the FSP model. Moreover, employees must be given a clear vision of career development opportunities that are available, especially in light of more routine tasks being given to the FSP. In this manner, they see the value of their contributions and will be engaged and supportive.

A good example would be to assign CDM staff to perform core functions, such as making final decisions on edit check specifications, or lead projects while FSPs take on a supporting role. Employees can be surveyed on their satisfaction to gain insightful information about the status of the FSP partnership at the individual level – knowledge that can be applied to further enhance the partnership.

### The Unexpected Limitation

Some clinical data management system (CDMS) vendors may require a contractual business relationship as a training support prerequisite. These vendors will only provide training support to an FSP if such a business relationship between the vendor and the FSP exists. FSPs may not be able to support certain tasks because they couldn't get the training. This not only limits the scope of tasks the FSP can perform, but poses a challenge to the partnership.

Some sponsor companies may opt to fill the gap by providing the training directly to FSPs, but not everyone has this

option. This creates an additional resourcing burden to the sponsor companies, as they have another responsibility for training FSPs. One may question the efficiency and effectiveness of this approach, and sponsor companies may turn to consider other FSPs capable of supporting CDM tasks without limitation.

### Conclusion

The FSP model can be an effective tool in the changing work environment in CDM. A true partnership is much more than a series of joint activities. It entails devotion and consistent planning, effort and resources. The trio of timeline, cost effectiveness and quality is the common key measurement in evaluating the success of an FSP model. But internal staff satisfaction and support deserve to be added to this equation as well.

Clear and transparent expectations will minimise many issues that can affect an FSP partnership. As we always say in CDM, never assume. It is the joint responsibility of the sponsor and the provider to ensure each FSP employee involved in CDM tasks is qualified. Their education, training and experience must be thoroughly evaluated and followed through. Like many other partnerships, an FSP partnership relies on a comfortable work relationship where each partner is confident that they are working on the same page. ■

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## Upcoming 2010 Webinars

Outsourcing Strategy and Methodology: Making it a “Win-Win” *July 15 & 22*

Protocol Review *August 12 & 19*

Touch Point/Hand Offs (with SAE Reconciliation) *September 16 & 23*



# Virtual Teams/ Project Management

Subha Krishnan, B.A, CCDM

Virtual teams are becoming prevalent within the Pharma/Bio-tech industry with more and more studies being conducted globally. Consequently, the management of virtual teams is becoming a common practice. The continued rise of the Internet and development of collaborative software have instilled new dimensions into project management as well.

Virtual project management is the system by which virtual teams collaborate for a finite period of time towards a specific goal. In our industry, the virtual teams come together to complete a study. There are many advantages to virtual teams. Companies are now able to attract the best workers independent of location, without needing to relocate; thereby benefitting from the increased flexibility, reduction in travel time and expense. The worker also is now able to concentrate on work and not worry about commute time and cost.

The effectiveness of the project manager is a key to the success of virtual teams. The project manager is the center of the whole process and ensures information gets accumulated and also disseminated to all members of the team.

In order for organizations to ensure effective use of virtual teams:

- processes for team management and development have to be designed, defined, piloted, tested and refined
- project managers have to be trained on virtual team management strategies
- team members have to be trained on new processes
- the culture of the organization has to be reshaped to support new structures and processes
- organizational structures have to be modified to reflect new team dynamics
- rewards systems have to be updated to reflect new team structures
- new information technology (IT) systems have to be deployed to support teams
- new management, measurement and control systems have to be designed

There are some critical aspects of a virtual project manager's mindset that must shift in order to be effective:

- | From:  | To:  |
|--|--|
| • Only Face to Face will work                                      | • Different kind of environments can support quality interaction   |
| • When the communication process breaks down, blame the technology | • When the communication process breaks down, evaluate the management and interaction strategies, not just the technical tool. |

Managing a virtual team meeting is like managing a face-to-face team meeting: effective meetings don't happen by chance. Virtual meeting experiences can be frustrating and disappointing when interaction with others in the group results in information overload, topic drift or conversations that are just not all that valuable. An explicit purpose is the most critical factor in determining the success of a virtual team. Lacking face-to-face meetings, a virtual team may need more frequent and more explicit check-ins about their purpose. On the up side, the technology environment may provide some advantages because it provides multiple ways to remind team members about purpose (as well as goals, tasks, timings) as part of the daily fabric of their communication.

In a face-to-face group, managers watch body language, facial expression and other signals to develop a sense of what is going on. Participants in virtual teams convey this same information in different ways. It is important to find ways to base your sense of what's happening on data. Frequently impressions of what is happening can be off-base because we're not used to reading the cues people give out via new media.

Some of the key ideas to keep in mind to make sure a virtual team works effectively include:

- teamwork is fundamentally social
- knowledge is integrated in the life of teams and needs to be made explicit
- it's important to create ways for team members to experience ownership
- knowledge depends on engagement in practice, people gain knowledge from observation and participation
- "failure" to perform is often the result of exclusion from the process

In conclusion, virtual teams are fast becoming more the rule than the exception in organizations. It is time to stop thinking of them as a special case and start developing strategies for dealing with the new challenges they create. Virtual teams need the same things all teams need - a clear mission, an explicit statement of roles and responsibilities, communications options which serve its different needs, opportunities to learn and change direction. The job of the project manager of a virtual team is to help the team learn how to be a virtual team and, most of all, to create ways to make the working of the virtual team visible to itself. But the most important thing to remember is that managing a virtual team is basically about managing a team. ■

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# Data Considerations for Implementation of an Adaptive Clinical Trial

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While many of you may not have had the opportunity to work on an adaptive design clinical trial, I would bet that most of you have heard about these

types of trials and may be working on one in the near future. An adaptive design clinical trial uses accumulating data to decide how to modify aspects of the study without undermining the validity and integrity of the trial.<sup>1</sup> Adaptations are prospectively defined, and the impact of the planned changes on the trial conclusions is understood prior to initializing the trial. The goal of adaptive trials is to make the studies more efficient (e.g. shorter duration, fewer patients), more likely to demonstrate an effect of the drug if one exists, or more informative (e.g. by providing broader dose-response information). Adaptive design trials also minimize patient exposure to potentially harmful and un-efficacious experimental treatments.

Adaptive design trials require more up-front planning than traditional trials to address statistical and operational considerations and to include time for potential regulatory interactions. Implementing an adaptive design trial requires cross-functional consideration and planning in order to execute effectively. Since the adaptive (interim) analysis relies on accumulating data, the clinical data manager (CDM) is a key driver of many of the discussions that need to occur with regards to the data flow. The CDM needs to be involved early in the study planning process to gain an understanding of the study design and data needs to be able to influence how best to provide the data for the interim analysis. Here are some key questions that the CDM should discuss with their study team in order to be able to define the study data flow.

- What key data points are needed for the interim analysis to drive design changes?

- What is the source of each of the key data points (e.g. Electronic Data Capture (EDC), central labs, Interactive Voice or Web Randomization System, other ancillary data)?
- If the key data is from multiple data sources, how will the key data be integrated?
- What is the study team's expectation for site data entry and for cleaning/validation of the key data?

Generally, an adaptive analysis utilizes only a small number of data points (key efficacy or safety measures). The CDM needs to understand what those key data points are, where they are being collected, and what the team's expectation is for cleaning of this data. For example, the interim analysis for a dose escalation study may only require the patient identification number, visit number, dose, and dose limiting toxicity, which may all be collected on the eCRF, and the team expectation is that this data will be monitored and validated prior to the adaptive analysis. With this information, the CDM can ensure that the sites understand the need for timely data entry of the 4 key data points (perhaps within 48 hours of patient visit). The CDM can also ensure that the Data Management Plan includes the expectation around validation of these data points (e.g. key data reviewed and query sent within 48 hours of data entry). If the key data needed for adaptive analysis is from multiple data sources, it is important to understand and document in the data flow diagram where data integration will occur (e.g. within EDC system, in another database, or in analysis data sets).

- If the study is blinded, but the data needs to be unblinded for adaptive analysis, who will prepare the unblinded data and how will the appropriate security access to unblinded data be maintained?

It is important that members of the study team do not have access to unblinded

data. The team needs to determine who will prepare the unblinded data for analysis. The statistician should document the unblinding plan as part of the study Statistical Analysis Plan.

- What format does the data need to be in for the adaptive analysis program or tool (e.g. .csv, .xml, Study Data Tabulation Model (SDTM), Statistical Analysis Software (SAS))?
- Where will the data 'snapshot' (extracted data, as well as any 'transformed' data used as analysis input) and the analysis output (including adaptive decision) for each adaptive analysis be archived?

The raw extracted data, as well as any transformed data (e.g. different data format or subset of data), and the output from the adaptive analysis must be archived so the adaptive analysis can be recreated if required.

- What is the frequency of data delivery for interim analyses (e.g., bi-weekly, after completion of each cohort, after 10 patients have completed a specific visit)?
- What is the expected data flow from collection to integration to analysis to archival?
- Is an internal or external data monitoring committee involved in the study? If so, what data does the committee need to see and how will they receive it? Do secure web portals or transfer routers need to be established?

It is also important that the CDM work with the study team to carefully design and document the entire data flow. A comprehensive data flow diagram should be developed (Figure 1). The CDM should ensure that the diagram includes the flow of data to and from external vendors and to data monitoring committees, if applicable. It is also critical that the data flow accounts for all security permis-

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# Data Considerations for Implementation of an Adaptive Clinical Trial

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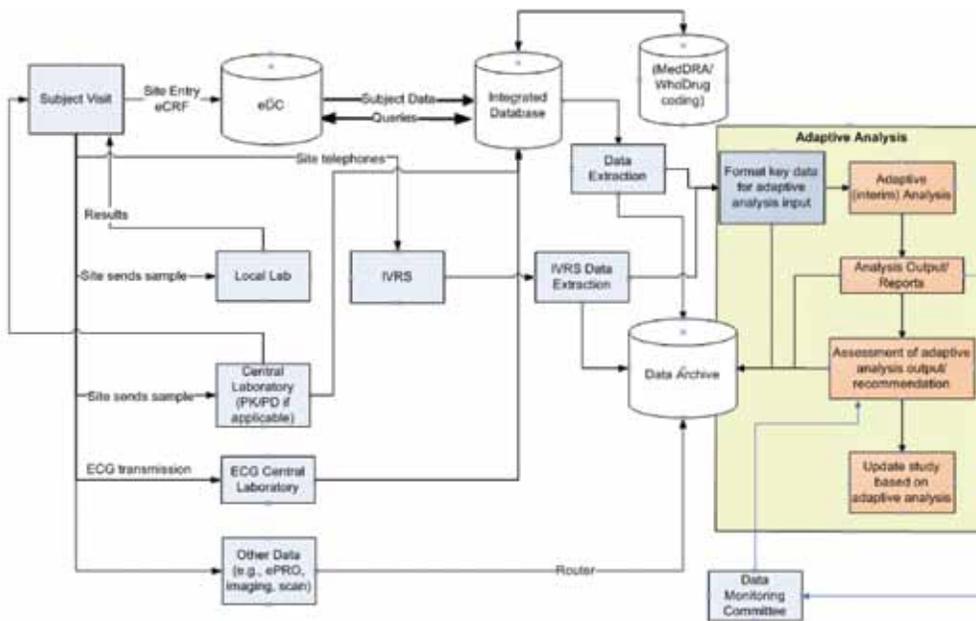


Figure 1. Example Data Flow Diagram

sions with regards to unblinded data to ensure the validity of the study is not compromised. In addition, the entire data flow should be fully tested prior to implementation. It is preferable that the data flow be tested using actual study data if time allows prior to the first interim analysis. However, data flow testing can also be completed by using ‘mock’ data (e.g. the EDC user acceptance testing data or created data). The testing should be con-

ducted with enough time available to address any issues, and retest if needed, prior to the first interim analysis.

Depending on the complexity of the study and the data flow, it may also be important to identify data flow risks and develop appropriate mitigation plans for each of the risks. Specific risks may be around the actual data flow (e.g. transfers); ensuring timely data entry by the sites; maintaining appropriate level of

data cleaning; or maintaining data blinding and data security. A data flow responsibilities matrix and a communication plan should be developed as well, to ensure it is clear who is responsible for monitoring each portion of the data flow and to define how any issues will be communicated.

In summary, the key to successfully implementing an adaptive design clinical trial is to have reliable key data available to enable the completion of the adaptive analysis and subsequent study updates to occur as planned. The responsibility for delivering the reliable data rests on the CDM. While this may sound rather daunting, it really is what CDMs must do for every clinical trial. The only difference is that an adaptive trial may require more cross-functional planning earlier in the study development process, with the CDM ensuring that all data-related decisions are well thought through and documented.

Good luck with implementing your adaptive trials, and remember to be ADAPTIVE! ■

*Marcia has a B.A. in Microbiology from Miami University, Oxford, OH, and has over 20 years of experience in the pharmaceutical industry, with the first 16 years in research the past 7 years in data management. Marcia also works with study teams to efficiently design and implement adaptive design studies.*

1. Gallo P, et al *Adaptive Designs in Clinical Drug Development - An Executive Summary of the PhRMA Working Group. Journal of Biopharmaceutical Statistics, 2006;16, 275-283*

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**A**utomate data flow process as much as possible  
**D**ocument everything!  
**A**nticipate potential issues and design mitigation plans  
**P**lan, Plan, Plan  
**T**est all aspects of data flow  
**I**nvolve other functions earlier in study development  
**V**endor oversight / communication is key  
**E**nsure appropriate security measures are in place

# Virtual Study Groups

Lisa A. Weir, Executive Director, Data Management, PharmaNet Development Group



As new communication technologies continue to emerge, Virtual Study Groups (VSG) are becoming a popular alternative to traditional learning methods. VSGs provide a learning environment in which employees can study materials and share information in a better and richer manner than utilizing self-study methods.

In the case of preparing for the SCDM CCDM exam, we expect that employees who work collaboratively in a VSG focused on the Good Clinical Data Management Practices (GCDMP) and other documents used in preparing for the certification exam can and will improve their chances of passing the exam and becoming certified. Participation in such a VSG allows each participant to share ideas and thoughts and ultimately learn from others.

While most VSG's are created by students, PharmaNet's VSG was created and is managed by those of us who have taken and passed the CCDM exam. This format allows us to present materials that will be covered by the exam as well as to provide helpful guidance on how to actually take the exam when the day arrives. Our virtual study presentation team is made up of employees who have taken and passed the exam as well as subject matter experts who desire to become a Certified Clinical Data Manager. Our CCDM VSG is global: eligible staff members from all of our locations around the world are encouraged to join the CCDM VSG.

Setting up a successful CCDM exam VSG requires determining which technology to use, knowing how to utilize the technology in the most efficient manner possible and ensuring all participants in the VSG know how to use the chosen technology and have appropriate access. The CCDM VSG should follow a structured agenda over a series of sessions and allow enough time for each topic to be covered appropriately. Setting up the

sessions requires accounting for time zone differences when the CCDM VSG is meeting in a global environment. For example, "Lunch and learn" sessions in the US become end of day sessions in the UK and Europe, and "Breakfast and learn" sessions in the US become end of day sessions in India.

In our VSG the CCDMs have some leeway on how they want to present the material. Most create slides and questions utilizing the GCDMP as their base. These are presented to the VSG in a one hour session. The attendees are expected to read the scheduled GCDMP chapter and come prepared to discuss the contents of the chapter. We have noticed the following:

- Fewer slides and more sample exam questions solicit more discussion in some regions
- When the polling feature of the software is used, there is a greater tendency for everyone to try to answer the sample questions, but it still may not stimulate discussion amongst all regions.

This is our fourth VSG and we still don't feel we have the right format. We will continue to experiment until we feel we have it just right. ■



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# Virtual Dream Team in Data Management

Victoria Guagliardo, Project Leader in Global Data Management and Standards at Schering-Plough, Inc. (Merck US); Shilpa Patel, Project Manager in Global Data Management and Standards at Merck; Victoria Rizvi, Project Manager in Global Data Management and Standards at Merck



It is 9:30 am in New Jersey, 8:30 am in Texas and 11:30 am in Argentina, South America. The Virtual Dream Team is at work. Some of us are just having our first cup of coffee while some are getting ready for lunch. Some of us are in casual attire while some are in business attire. Our virtual team is a dream team. We do not have necessarily all the best players, but it does consist of enough talent that the team itself is stronger as a result of the sum of the individual talents of its members. In today's world more and more companies including pharmaceutical are leaning toward utilizing virtual teams. The nature of teams has changed significantly because of changes in organizations and the nature of the work they do. Teams have become more diverse in composition.<sup>1</sup> Members now work from different geographical locations, including home offices. We have found that our data management dream team at Merck is no exception.

## What is a Virtual Team?

Traditional teams are not what they used to be. Companies have discovered the value of collaborative work. There is a new emphasis on knowledge management - harvesting the learning of the experience of members of the group so that it is available to everyone.<sup>1</sup>

A virtual team is a group of individuals who work across time, space, and organizational boundaries. They have complementary skills, are committed to a common purpose, have interdependent performance goals, and share an approach to work for which they hold themselves mutually accountable. Geographically dispersed teams allow the organization to hire and retain the best people regardless of their location.<sup>2, 3, 5</sup>

## Virtual Team/ cross functional team

Our data management dream team has various levels across the globe: a Manager working from a home office in Indiana, Project Managers and Clinical Data Coordinators working from home offices spread across North America and a regional team in Argentina. They interact with data management contractors and other functional areas (i.e. clinical monitors, clinical programming, statistics, etc.) around the world. Our Virtual Dream Team has experience and works day-to-day on all clinical trial activities from database design/start up to database lock. The team has successfully completed submissions of multiple

clinical trials in various therapy areas. For example, during the last few years our group has worked on major programs in the Allergy, Asthma and HIV therapy areas. Our virtual team successfully completed multiple database locks and interim analyses. "We used to think that meeting face-to-face was the only way to build trust and teamwork. Armed with new technology and new best practices, we're learning new ways to connect on a human level with people anywhere, anytime," said Dr. Jaclyn Kostner, author of *Virtual Leadership*.<sup>7</sup>

## Communication

Creating and maintaining trust in a global virtual team whose members transcend time, space, and culture is challenging. Communication builds trust. It provides guidance, and the phrase "collaborative teams" infers that communication is taking place.<sup>3</sup>

Concerning communication, we considered volume and quality of the information transported across time and space. Individuals can convey information, which includes providing immediate feedback, utilizing multiple cues and channels, and allowing personalization and language variety.<sup>4, 5</sup>

The issue of communication can often be technological in nature. In many cases, it is a problem that occurs because of poor communication skills on the part of the team members. Cultural diversity, both national and linguistic, is an additional factor to consider.

Our team has worked hard to overcome these challenges. How did we succeed? Communicating effectively and using technology that fits each situation; building working relationships based on mutual trust, respect, fairness and affiliation among project team members. We are leading by example, establishing shared goals, expectations, purpose and vision.<sup>4, 5, 6</sup> Although we are geographically dispersed, our team was also able to build a close personal relationship. We share personal pictures and stories via email and fun facts about each other during staff meetings.

## Location/ time zone

Depending on the time of year, the time difference between the North America and South America can be from one to four hours, but we make it work. The team respects each other's working hours and adjusts schedules and work assignments accordingly. Of course, crunch time has no time restrictions - we all work as late as we have to and at the same time we do watch out for each other to make sure that no one routinely has "dinner-time" meetings. Our time difference has benefits too - colleagues in Argentina are closer in time to our clinical sites

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## Virtual Dream Team in Data Management

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in Europe and can facilitate work before the East Coast team starts their day. It is a tag team effort: members in Argentina can send out queries early in the morning for issues which US colleagues identified late the day before or US colleagues can complete review of what colleagues in Argentina did not have a chance to complete by the end of a busy day (which ends before the US business day).

### **Technology/ Efficiency**

The growth we are seeing is enabled by technology – e-mail, web and video conferencing, high-speed internet connections, phone, fax and instant messaging all are forms of communication used by individuals on a day-to-day basis. With clinical trials conducted around the world, technology has helped us work efficiently. Working hours within a day are extended and we are able to literally work around the clock. This advantage of technology and time allows for data management to successfully meet deliverables.

In contrast there are also some limitations of technology and efficiency. “A recent context switching study conducted by Microsoft Research and the University of Illinois examined diaries of the daily tasks performed by a variety of users. What they found was that 45% of the reported tasks in the diaries were project-related or routine tasks that were part of the users’ jobs. That figure would be astounding on its own, but when considered along with the tasks that comprise the other 55%, you’ll really be amazed: 23% of the daily tasks were related to e-mail and 13% were related to tracking their multiple tasks. That’s 36% of time spent managing email and tasks! The remainder of the tasks was pretty evenly split between phone calls (8%), meetings (6%), and personal time (5%).”<sup>8</sup> Our team has fallen prey to similar patterns, especially with regards to emails. There are etiquettes to be followed and our company has established some ground rules that aid communication to be faster and easier without a decrease in work quality and efficiency. There are several solutions to the issue including e-mail free Fridays, closing Outlook, disabling IM client, turning off cell phones, and so forth. They’ve all been somewhat effective in creating more focus on the work itself.

### **Work-life balance**

Almost all members of our US team work from home. Currently only two of our team members come to NJ headquarter office twice a week. We save lots of commute time (and of course money on constantly rising gas prices) and can easily use that extra time to finish up pending work without feeling guilty for taking time from our families. It doesn’t mean that the team works during “commute” time every day, but having a flexibility of doing it helps to relieve pressure of trying to run out from the office at 5:00 pm on the dot to beat rush-hour traffic.

The Virtual Dream Team can definitely get a lot done at home office with less disruption. Yes, everyone needs an outlet to let off steam and a feeling of camaraderie. This is when we pick up the phone for a quick chat. It’s all about balance – the key is to know when to walk away from the ever present work when your office is at home.

Why Virtual Teams in data management?<sup>2</sup>

- Recruit talent from anywhere in the world
- Personal flexibility
- Increasing technological sophistication
- A flexible organization is more competitive and responsive to the marketplace
- Workers tend to be more productive – less commuting and travel time
- The increasing globalization of clinical trials
- The global workday is 24 hours vs. 8 hours

Mastering how to use these tools and techniques will distinguish teams that will succeed from those that will not.

### **References:**

- [1] Kimball, L., “Managing Virtual Teams” *Team Strategies Conference, Group Jazz.com* [online] <http://www.groupjazz.com/pdf/vteams-toronto.pdf> [retrieved 02 Mar 2010].
- [2] “Definition of Virtual Teams”, *Free management library* [online] [http://www.managementhelp.org/grp\\_skill/virtual/defntion.pdf](http://www.managementhelp.org/grp_skill/virtual/defntion.pdf) [retrieved 02 Mar 2010].
- [3] Rolfes, M., “Virtual Project Management”, *University of Missouri - St. Louise* [online] [http://www.umsl.edu/~sauterol/analysis/488\\_f01\\_papers/rolfes.htm](http://www.umsl.edu/~sauterol/analysis/488_f01_papers/rolfes.htm) [retrieved 08 Mar 2010].
- [4] Thompsen, J. A., “Leading Virtual Teams”, *Quality Digest* [online] <http://www.qualitydigest.com/sept00/html/teams.html> [retrieved 08 Mar 2010].
- [5] Jarvenpaa, S. L. and Leidner, D., “Communication and Trust in Global Virtual Teams”, *Journal of Computer Mediated Communication*, Vol. 3, No. 4, June 1998 [online] <http://jcmc.indiana.edu/vol3/issue4/jarvenpaa.html> [retrieved 08 Mar 2010].
- [6] Schlenkrich, L. and Upfold, C., “A Guideline for Virtual Team Managers: the Key to Effective Social Interaction and Communication” *Electronic Journal of Information Systems Evaluation*, Vol. 12, No.1, 2009, pp 109-118 [online] [http://www.ejise.com/volume-12/volume12-issue1/Schlenkrich\\_and\\_Upfold.pdf](http://www.ejise.com/volume-12/volume12-issue1/Schlenkrich_and_Upfold.pdf) [retrieved 08 Mar 2010].
- [7] “Virtual Work Trends” *EffectiveMeeting.com* [online], <http://www.effective-meetings.com/technology/virtualteam/mci10.asp> [retrieved 11 Mar 2010].
- [8] Spagnuolo, C., “The Myth of Managed Multi-tasking” *EdgeHopper.com* [online], <http://edgehopper.com/the-myth-of-managed-multi-tasking/> [retrieved 11 Mar 2010].

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