InSPiRe
Innovative Methodology for Small Populations Research
FP HEALTH 2013 – 602144

Deliverable Report

Deliverable N°:	D6.1
Deliverable Title:	Project and Communications Plans and Project Data Handling Policy
Work Package N°:	6
Lead Beneficiary N°:	1

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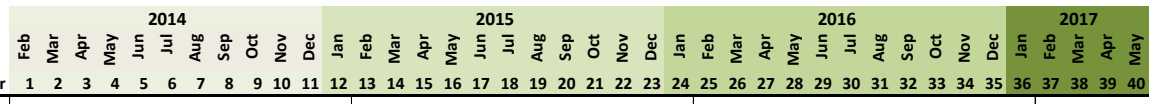
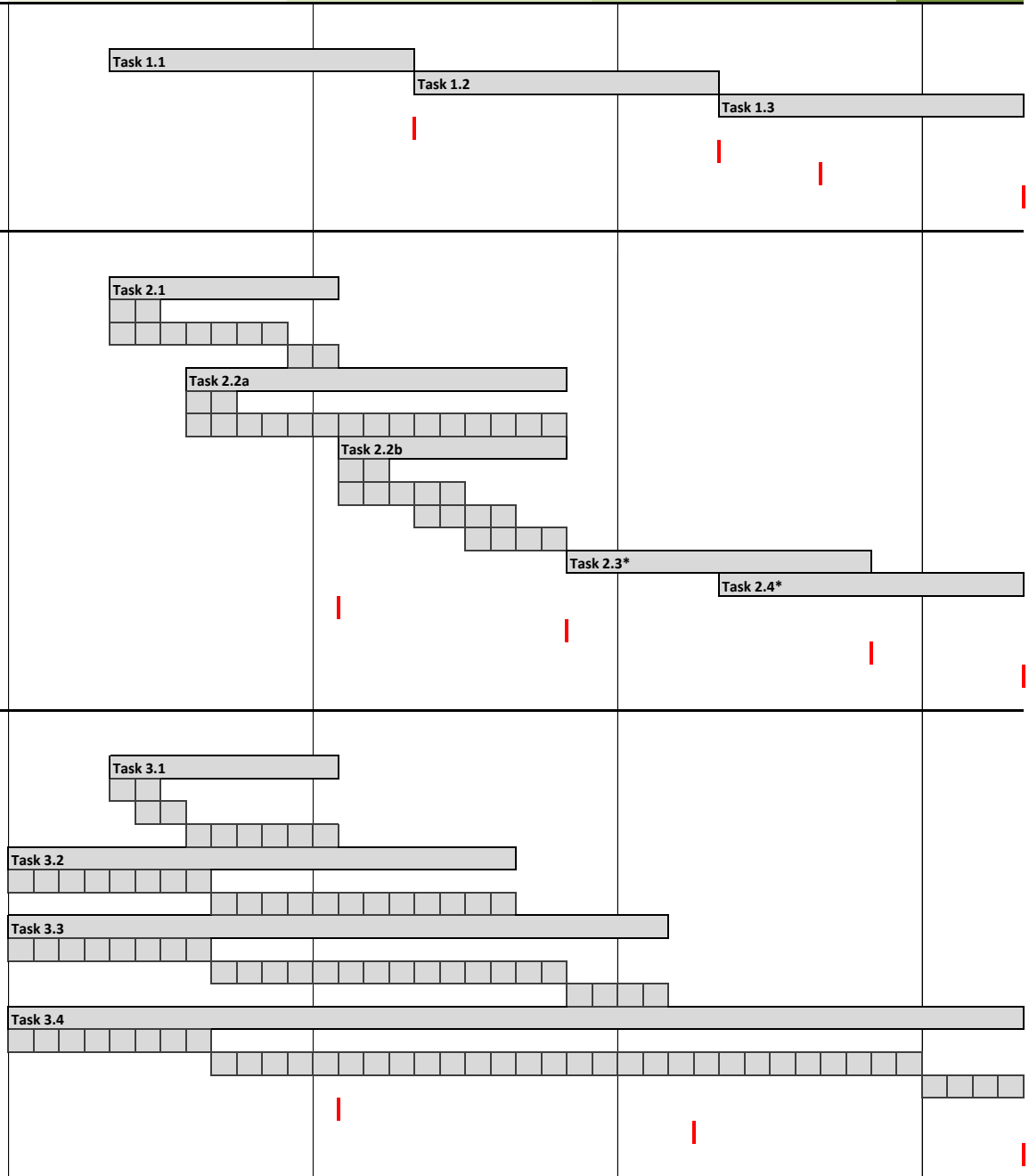
Deliverable Report 6.1 (Part 1):
Project Plan

InSPiRe Project Plan - Work Packages 1 to 6



Work Package 1 (WP1)

Task 1.1 Combining PK data for optimal dose-finding with categorical PD outcome
Task 1.2 Using continuous PD data
Task 1.3 Combining data from different sources
D1.1 Report on dose-finding case studies and comparison study methods
D1.2 Report on incorporation of PK outcomes in dose-finding studies and method for bridging studies
D1.3 Report on methods for handling two continuous outcomes in dose-finding studies
D1.4 Report on methodology for early phase dose-finding trials in small populations



Work Package 2 (WP2)

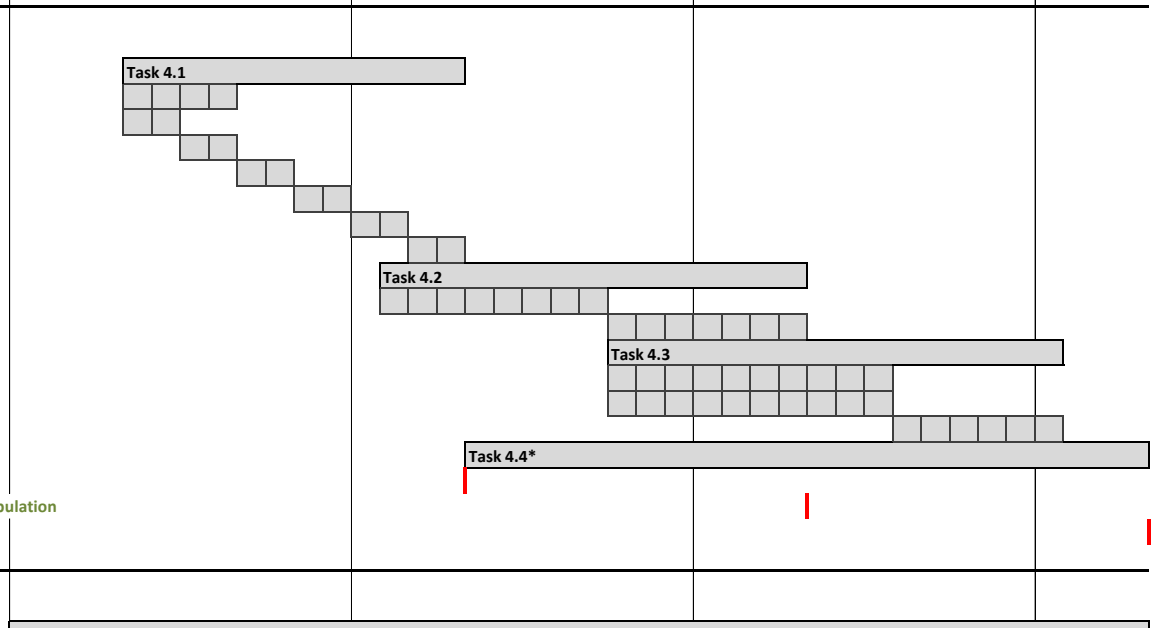
Task 2.1 Review of relevant literature
Task 2.1.1 Identify key literature
Task 2.1.2 Summarise and classify literature
Task 2.1.3 Write review
Task 2.2a Development of decision-theoretic framework
Task 2.2a.1 Review of relevant literature
Task 2.2a.2 Develop structure for decision-theoretic framework
Task 2.2b Construction of an appropriate utility function
Task 2.2b.1 Review of literature
Task 2.2b.2 Development of utility function
Task 2.2b.3 Apply to simple case-studies
Task 2.2b.4 Writing up
Task 2.3 Development of value-of-information approaches*
Task 2.4 Consideration of levels of evidence appropriate for decision-making in small populations*
D2.1 Report of literature review on decision theoretic methods in clinical trial design
D2.2 Report on decision-theoretic methods for clinical trials in small populations
D2.3 Report on value-of information methods for clinical trials in small populations
D2.4 Report on decision-theoretic designs for clinical trials in small populations

Work Package 3 (WP3)

Task 3.1 Literature review
3.1.1 Study of Review Papers
3.1.2. Keyword Search in Databases and manual assessment of found records
3.1.3 Collating of Literature, writing of report
Task 3.2 Development and assessment of frequentist methods
3.2.1 Investigation of basic fixed sample trial designs
3.2.2 Development of more general trial designs based on frequentist hypothesis testing
Task 3.3 Development of decision-theoretic methods for subgroup identification
3.3.1 Setup of a utility based framework for clinical trial designs
3.3.2 Extension of the elementary framework to cover more realistic models
3.4.3 Writing of report
Task 3.4 Adaptive enrichment trials
3.4.1 Setup of a basic framework for adaptive clinical trial designs
3.4.2 Development of trial designs with adaptive selection rules
3.4.3 Writing of report
D3.1 Report on literature review on methods for identification and confirmation of targeted subgroups
D3.2 Report on methods for identification and confirmation of subgroups with risk-benefit balance
D3.3 Report on methods for adaptive enrichment trials

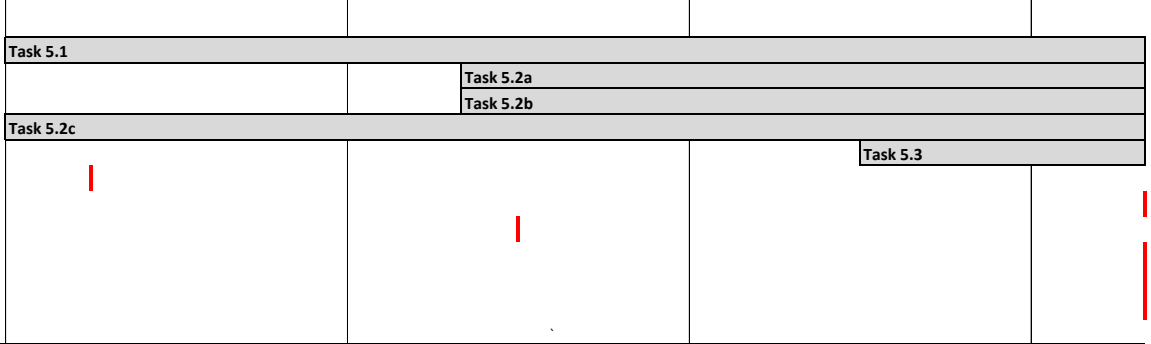
Work Package 4 (WP4)

Task 4.1 Systematic literature review
Sub-task 4.1.1 Literature search
Sub-task 4.1.1.1 Searching electronic databases
Sub-task 4.1.1.2 First and second-stage screening
Sub-task 4.1.2 Data extraction
Sub-task 4.1.3 Quality appraisal
Sub-task 4.1.4 Data analysis and interpretation of results
Sub-task 4.1.5 Reporting of systematic review
Task 4.2 Evidence synthesis for a single trial
Sub-task 4.2.1 Evidence synthesis for the analysis of a single trial
Sub-task 4.2.2 Evidence synthesis for the planning of a single trial
Task 4.3 Borrowing strength between trials
Sub-task 4.3.1 Hierarchical modelling
Sub-task 4.3.2 Sensitivity analysis
Sub-task 4.3.3 Applications
Task 4.4 Development of software to implement methods*
D4.1 Report on literature review on methods for evidence synthesis in planning of small population clinical trials
D4.2 Report on evidence synthesis methods to support the planning, analysis, and interpretation of a clinical trial in a small population
D4.3 Report on evidence synthesis methods in small populations



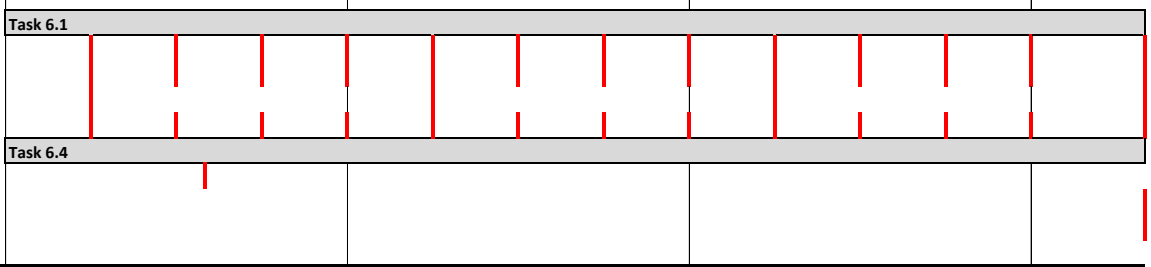
Work Package 5 (WP5)

Task 5.1 Creation and maintenance of project website
Task 5.2a Publication of project results in peer-reviewed journals
Task 5.2b Presentation of project results at relevant conferences
Task 5.2c Disemination of project aims and results to general public and patients
Task 5.3 Planning and conduct of project conference
D5.1 Project website
D5.2 Maintenance and updating of project website
D5.3 Dissemination, use and exploitation of foreground plan
D5.4 Dissemination to the general public and patients
D5.5 Dissemination via publication in peer reviewed journals and at national or international conferences
D5.6 Project conference



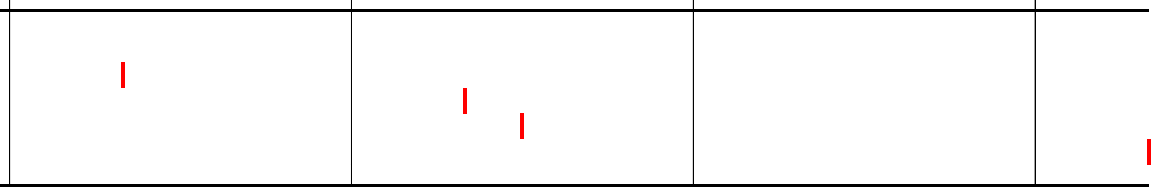
Work Package 6 (WP6)

Task 6.1 Establish and maintain project management structures
Task 6.2 Management committee meetings
Task 6.2a Steering committee meetings
Task 6.2b Independent Scientific Advisory Committee meetings
Task 6.3 Work package team meetings
Task 6.4 Ethical, data protection and legal issues
D6.1 Project and communications plans and project data handling policy
D6.2 Project committee meetings
D6.3 Documentation of compliance with all necessary ethical, data protection and legal requirements



Milestones

MS1 Appointment of research fellows (WP6)
MS2 Completion of literature reviews and initial reports (WP1, WP2, WP3, WP4)
MS3 Completion of interim reports (WP1, WP2, WP3, WP4)
MS3 Completion of final report (WP1, WP2, WP3, WP4, WP5)



* Sub-tasks and/or further details to be provided by WP leaders as the project progresses

InSPiRe Project Plan - Work Package 1

Work Package Lead: Sarah Zohar (INSERM)

Tasks	Task description	Estimated duration of task and start date	Person(s) responsible for task	**Dependancies** (please state if the task is dependent on the completion of another task/sub-task or whether there are any other dependancies	**Risk Assessment** (please identify any potential risks that could prevent the task being completed, either in its completeness, or on time, and its impact on other tasks/deliverables. Identify actions that could be taken to mitigate the risk)	**Deliverables** (Please state the deliverable(s) linked to this task - D1.1, D1.2, D1.3 or D1.4)
Task 1.1 Combining PK data for optimal dose-finding with categorical PD outcome	Improve informativeness of design in children, learning about the PK/PD relationship during the trial and guiding dose selection by modelling also this relationship and not only the dose-toxicity relationship. Toxicity is binary (or categorical) variable. Identification of case-studies: ideally one or two real-life case-studies.	12 months, Start Jun 2014	Sara Zohar, Emmanuelle Comets, Moreno Ursino, Frederike Lentz, Corinne Alberti	None	None	D1.1
Task 1.2 Using continuous PD data	Explore methods handling two continuous outcomes with underlying latent PD variable controlling both efficacy and toxicity.	12 months, Start Jun 2015	Sara Zohar, Emmanuelle Comets, Moreno Ursino, Frederike Lentz	Task 1.1	There could be computational problems. Action: approximations.	D1.2, D1.3
Task 1.3 Combining data from different sources	Extract relevant information to build priors for the methods developed in 1.1 and 1.2, handling multiple sources of data and assessing influence of priors.	12 months, Start Jun 2016	Sarah Zohar	Task 1.1 and task 1.2	There could be computational problems. Action: approximations.	D1.4
DELIVERABLES **D1.1 Report on dose-finding case studies and comparison study methods (Due: May 2015)** **D1.2 Report on incorporation of PK outcomes in dose-finding studies and method for bridging studies (Due: May 2016)** **D1.3 Report on methods for handling two continuous outcomes in dose-finding studies (Due: Sept 2016)** **D1.4 Report on methodology for early phase dose-finding trials in small populations (Due: May 2017)**						

InSPiRe Project Plan - Work Package 2

Work Package Lead: Nigel Stallard (Warwick)

Tasks	Task description	Estimated duration of task and start date	Person(s) responsible for task	**Dependancies** (please state if the task is dependent on the completion of another task/sub-task or whether there are any other dependancies	**Risk Assessment** (please identify any potential risks that could prevent the task being completed, either in its completeness, or on time, and its impact on other tasks/deliverables. Identify actions that could be taken to mitigate the risk)	**Deliverables** (Please state the deliverable(s) linked to this task - D2.1, D2.2, D2.3 or D2.4)
Task 2.1 Review of relevant literature		9 months, Start Jun 2014			Little risk other than that arising from staff absence due to sickness etc.	D2.1, D.2.4
Task 2.1.1 Identify key literature	Identify relevant key literature	2 months, Start Jun 2014	Siew Wan Hee			
Task 2.1.2 Summarise and classify literature	Arrange literature for review	7 months, Start Jun 2014	Siew Wan Hee	Task 2.1.1		
Task 2.1.3 Write review	Prepare paper for submission and report for deliverable	2 months , Start Jan 2015	Siew Wan Hee, Nigel Stallard	Tasks 2.1.1 and 2.1.2		D2.1, D2.4
Task 2.2a Development of decision-theoretic framework		15 months, Start Sept 2014			Little risk other than that arising from staff absence due to sickness etc.	D2.2, D2.4
Task 2.2a.1 Review of relevant literature	Identify and review relevant key literature	2 months, Start Sept 2014	Siew Wan Hee, Nigel Stallard + WP team	Task 2.1.1		
Task 2.2a.2 Develop structure for decision-theoretic framework	Develop decision-theoretic framework for clinical trials along with suitable (simple) utility function	15 months, Start Sept 2014				
Task 2.2b Construction of an appropriate utility function		9 months, Start Mar 2015			Timelines look quite tight on this task - we could perhaps start this earlier	
Task 2.2b.1 Review of literature	Review literature for relevant examples	2 months, Start Mar 2015	Siew Wan Hee, Nigel Stallard			
Task 2.2b.2 Development of utility function	Develop and implement utility function	5 months, Start Mar 2015	Siew Wan Hee, Nigel Stallard	Task 2.2a, Task 2.2b.1		
Task 2.2b.3 Apply to simple case-studies	Work up some simple applications to show how methods might be applied in practice	4 months, Start Jun 2015		Task 2.2a.2, Task 2.2b.2		
Task 2.2b.4 Writing up	Prepare paper for submission and report for deliverable	4 months, Start Aug 2015	Siew Wan Hee, Nigel Stallard + WP team	Task 2.2b.3	Risk that work from earlier tasks may be running late - need to check time is left for report writing	D2.2
Task 2.3 Development of value-of-information approaches*		12 months, Start Dec 2015	Siew Wan Hee, Jason Madan, Nigel Stallard			D2.3, D2.4
Task 2.4 Consideration of levels of evidence appropriate for decision-making in small populations*		12 months, Start Jun 2016	Siew Wan Hee, Nigel Stallard			D2.4

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D2.1 Report of literature review on decision theoretic methods in clinical trial design (Due February 2015)

D2.2 Report on decision-theoretic methods for clinical trials in small populations (Due November 2015)

D2.3 Report on value-of information methods for clinical trials in small populations (Due November 2016)

D2.4 Report on decision-theoretic designs for clinical trials in small populations (Due May 2017)

* Sub-tasks and/or further details to be provided by WP leaders as the project progresses

InSPiRe Project Plan - Work Package 3

Work Package Lead: Martin Posche (MUW)

Tasks	**Task description**	**Estimated duration of task and start date**	**Person(s) responsible for task**	**Dependancies** (please state if the task is dependent on the completion of another task/sub-task or whether there are any other dependancies	**Risk Assessment** (please identify any potential risks that could prevent the task being completed, either in its completeness, or on time, and its impact on other tasks/deliverables. Identify actions that could be taken to mitigate the risk)	**Deliverables** (Please state the deliverable(s) linked to this task - D3.1, D3.2, D3.3)
Task 3.1 Literature review		9 months, Start Jun 2014	Thomas Ondra, Martin Posch		Little risk other than that arising from staff absence due to sickness etc.	D3.1
3.1.1 Study of Review Papers	Identify seminal papers	2 month, Start June 2014				
3.1.2. Keyword Search in Databases and manual assessment of found records	Broader Search in Databases	2 month, Start July 2014				
3.1.3 Collating of Literature, writing of report	Structuring and summarizing results	6 month, Start September 2014				
Task 3.2 Development and assessment of frequentist methods		20 months, Start Feb 2014	Thomas Ondra, Martin Posch			D3.2
3.2.1 Investigation of basic fixed sample trial designs	Definition of fixed sample trial designs considering hypothesis in multiple populations that control the type I error rate	8 month, start Feb 2014				
3.2.2 Development of more general trial designs based on frequentist hypothesis testing	Definition of trial design parameters, formulation of multiple testing strategies	12 months, Start Oct 2014			Little risk other than that arising from staff absence due to sickness etc.	
Task 3.3 Development of decision-theoretic methods for subgroup identification		26 month, Start February 2014	Thomas Ondra, Martin Posch		Little risk other than that arising from staff absence due to sickness etc.	D3.2
3.3.1 Setup of a utility based framework for clinical trial designs	Definition of elementary utility functions for enrichment designs	8 month, Start February 2014				
3.3.2 Extension of the elementary framework to cover more realistic models	Extension to more complex utility functions and trial designs	14 month, Start October 2014		D3.1		
3.4.3 Writing of report		4 month, Start December 2015				
Task 3.4 Adaptive enrichment trials		40 month, Start February 2014	Thomas Ondra, Martin Posch		Little risk other than that arising from staff absence due to sickness etc.	
3.4.1 Setup of a basic framework for adaptive clinical trial designs	Definition of an elementary class of adaptive trial designs	8 month, Start February 2014				
3.4.2 Development of trial designs with adaptive selection rules	Definition of advanced more general adaptation rules and evaluating the properties of different design options, optimization of design parameters	28 month, Start October 2014		D3.1		D3.3
3.4.3 Writing of report		4 month, Start December 2015				
DELIVERABLES						
D3.1 Report on literature review on methods for identification and confirmation of targeted subgroups (Due Feb 2015)						
D3.2 Report on methods for identification and confirmation of subgroups with risk-benefit balance (Due Apr 2016)						
D3.3 Report on methods for adaptive enrichment trials (Due May 2017)						

Notes: The timing and order of tasks within WP3 have been adjusted and no longer reflect the timing and order outlined in Annex 1 Description of Work. However, please note this does NOT have any impact on the objectives of the project, the tasks have stayed the same. We found that it is most efficient to address tasks 3.2, 3.3 and 3.4 in an integrated way. We defined a general class of adaptive clinical trial designs that includes classical fixed sample designs that allows for a powerful comparison of different design options in a unified way. Furthermore, we are using decision theoretic methods to optimise fixed sample and adaptive trial designs. Therefore, we proposed to work on the tasks in parallel to make best use of the progress in the different tasks when working on problems in parallel tasks. We have extended the timescales for tasks 3.2, 3.3 and 3.4 and planned that they proceed in parallel.

InSPiRe Project Plan - Work Package 4

Work Package Lead: Tim Friede (UMG-GOE)

Tasks	Task description	Estimated duration of task and start date	Person(s) responsible for task	Dependencies (please state if the task is dependent on the completion of another task/sub-task or whether there are any other dependencies)	Risk Assessment (please identify any potential risks that could prevent the task being completed, either in its completeness, or on time, and its impact on other tasks/deliverables. Identify actions that could be taken to mitigate the risk)	Deliverables (Please state the deliverable(s) linked to this task - D4.1, D4.2, D4.3)
Task 4.1 Systematic literature review	**Conducting a systematic review of evaluations of interventions in paediatric multiple sclerosis.**	**12 months, Start Jun 2014**	**Steffen Unkel, Christian Röver**		**The literature search might reveal that sufficient evidence to be included in a systematic review of evaluations of interventions in paediatric multiple sclerosis is not available. If so, the systematic review will focus on the use of evaluations of interventions in another rare condition.**	**D4.1**
Sub-task 4.1.1 Literature search	Selecting suitable primary studies to be included in the systematic review	4 months, Start Jun 2014	Steffen Unkel, Christian Röver			
Sub-task 4.1.1.1 Searching electronic databases	Using electronic databases such as PubMed, a systematic literature search will be carried out to identify relevant primary studies. The reference lists in all relevant publications will be examined for further relevant studies.	2 months, Start Jun 2014	Steffen Unkel			
Sub-task 4.1.1.2 First and second-stage screening	A first-stage screening of titles and abstracts is performed by two reviewers independently . Based on the initial screening, selected full-text articles are obtained for the second-stage screening, which is performed independently by two reviewers. The studies selected are then submitted for data extraction.	2 months, Start Aug 2014	Steffen Unkel, Christian Röver	Sub-task 4.1.1.1		
Sub-task 4.1.2 Data extraction	Using a standardized electronic form the following items will be extracted: reference, objective, study design, population, intervention, control, outcome, further comments.	2 month, Start Oct 2014	Steffen Unkel	Sub-task 4.1.1		
Sub-task 4.1.3 Quality appraisal	The methodological quality of studies included in the review is assessed independently by two researchers according to a set of formal criteria. Discrepancies in scoring will be resolved through discussion.	2 month, Start Dec 2014	Steffen Unkel, Christian Röver	Sub-task 4.1.2		
Sub-task 4.1.4 Data analysis and interpretation of results	Data analysis and interpretation of results of the included studies. Simple descriptive evaluation of each study, presented in tabular format. Discussion of strengths and weaknesses of the included studies. Conclusions to be based on the best available scientific evidence.	2 Month, Start Feb 2015	Steffen Unkel	Sub-task 4.1.3		
Sub-task 4.1.5 Reporting of systematic review	Write-up of the systematic review according to the PRISMA statement (PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses).	2 month, Start Apr 2015	Steffen Unkel	Sub-task 4.1.4		
Task 4.2 Evidence synthesis for a single trial	**Synthesizing evidence in the scenario of a single randomised controlled trial comparing an experimental treatment to a control in a small population.**	**15 months, Start Mar 2015**	**Steffen Unkel, Christian Röver**			**D4.2 and D4.3**
Sub-task 4.2.1 Evidence synthesis for the analysis of a single trial	Developing synthesis methods for the analysis of randomised controlled trials in small populations utilizing information external to the randomized comparison.	8 months, Start Mar 2015	Steffen Unkel, Christian Röver			
Sub-task 4.2.2 Evidence synthesis for the planning of a single trial	Proposing approaches for the planning of a randomised controlled trial in small populations by combining the data from the randomised controlled trial with non-randomised data.	7 months, Start Nov 2015	Steffen Unkel, Christian Röver			
Task 4.3 Borrowing strength between trials	**Developing methods to borrow strength between subgroups.**	**16 months, Start Nov 2015**	**Steffen Unkel, Christian Röver**			**D4.3**
Sub-task 4.3.1 Hierarchical modelling	Building hierarchical models with flexible distributions for the random effects to achieve robust inference.	10 months, Start Nov 2015	Steffen Unkel, Christian Röver			
Sub-task 4.3.2 Sensitivity analysis	Exploring the characteristics of the hierarchical structures in practically relevant scenarios through extensive simulation studies.	10 months, Start Nov 2015	Steffen Unkel, Christian Röver			
Sub-task 4.3.3 Applications	Applying the methodology to (a) paediatric trials borrowing from trials in adults and (b) compounds developed for multiple indications borrowing between indications.	6 months, Start Sept 2016	Steffen Unkel, Christian Röver	Sub-task 4.3.1 and sub-task 4.3.2		
Task 4.4 Development of software to implement methods*	**Implementation of the newly developed methodology in the free software environments R and WinBugs. Making the computer code publically available through the projects website. Posting an R package on CRAN (Comprehensive R Archive Network).**	**24 months, Start Jun 2015**	**Steffen Unkel, Christian Röver**	**Task 4.2 and task 4.3**		**D4.3**

DELIVERABLES

D4.1 Report on literature review on methods for evidence synthesis in planning of small population clinical trials (Due: May 2015)

D4.2 Report on evidence synthesis methods to support the planning, analysis, and interpretation of a clinical trial in a small population (Due: May 2016)

D4.3 Report on evidence synthesis methods in small populations (Due: May 2017)

* Sub-tasks and/or further details to be provided by WP leaders as the project progresses

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Deliverable Report 6.1 (Part 2):
Communication Plan

Communication Plan

Clear and transparent communication is critical to the successful delivery of the InSPiRe project. This communication plan has been prepared to detail the types of communications and the communication mechanisms that will be needed to ensure the project runs smoothly.

The communication plan covers 2 areas of communication:

1. Internal Communication Structure
    a. Communication within the InSPiRe team
    b. Communication between the InSPiRe team and the Independent Scientific Advisory Committee (ISAC)
    c. Communication between the coordinating institution (Warwick) and the partner's financial administrators)

2. External Communication Structure
    a. Communication between the University of Warwick and the European Commission
    b. Communication via the website and social media (public image)

Internal Communications Structure

As depicted in the Annex 1 Description of Work, each InSPiRe team member has different skill sets and varying levels of responsibility for the different components of the project (work packages 1 to 6).

The internal communication plan aims to achieve the following:

- To ensure **messages** are properly and **adequately disseminated**
- To establish clear communication channels to **prevent duplication of work** amongst the work packages
- To **leverage individuals skills** and ensure a **consistent and cohesive team approach**.
- Ensure that **risks are raised and addressed** in a timely manner
- To ensure **transparency and continuous learning** between the InSPiRe team members
- Foster an **organisational culture of information sharing,** where all staff are well informed and work toward the same goals
- Ensuring **clarity** on the role and **responsibilities** of the InSPiRe team members
- To ensure that work is carried out **efficiently, effectively,** and **meets the needs of stakeholders**

Content of Communication

Communication within the InSPiRe team primarily relates to the delivery of the work packages (WPs) and how the tasks of the various team members fit together and contribute to the goal of the project as a whole.

Communication may include:

- Brainstorming approaches to the various tasks within the WPs
- Coordinating inputs with other team members to ensure maximum efficiency
- Progress reporting
- Contributing to papers and other key documents
- Peer reviewing the work of other team members
- Updating team members about interactions with various stakeholders

Communication between the InSPiRe team and the Independent Scientific Advisory Committee (ISAC) is primarily to ensure that the work carried out by the InSPiRe team is relevant to key stakeholders (including patients and the public).

Communication may include:

- Advice and guidance on key project decisions
- Feedback on reports, deliverables and/or project progress
- Advice on dissemination and exploitation of project results

Communication between the coordinating institution (Warwick) and partner's financial administrators is primarily to ensure that the EU financial guidelines are being adhered to and to keep track of the project budget.

Communication may include:

- Financial rules
- Details of partners expenditure

All types of internal communications are coordinated by the Project Manager.

Communication Mechanisms

Communication mechanisms vary according to the content of the communication and the intended audience. The key communication mechanisms include meetings, an intranet site and group emails.

Meetings

A number of teleconferences (TCs) and face-to-face meetings will take place over the duration of the project.

Work Package (WP) Teleconferences (TCs)

The content of the WP meetings will be scientific and technical discussions relating to the particular WP. Each WP team will meet **at least once every 3 months**, and more regular meetings will be scheduled if required. Each institution will host the meeting for their WP as follows:

WP1: At INSERM or teleconference
WP2: At Warwick or teleconference
WP3: At MUW or teleconference
WP4: At UMG or teleconference

Steering Committee (SC) TCs and face to face meetings

The 'Steering Committee' is the decision-making body of the Consortium and comprises one member from each of the projects beneficiaries. However, all members of the InSPiRe project team are required to attend the steering committee meetings as observers, at the request of the Principal Investigator (PI). The content of the SC meetings will include a general business meeting to discuss the administrative and financial management of the project as well as a scientific discussion. The SC will meet **at least once every 3 months, via teleconference**, and **face to face on an annual basis**.

Independent Scientific Advisory Committee (ISAC) meetings.

The ISAC meeting will occur face-to-face on an **annual basis**. For convenience and to reduce travel costs, these will occur concurrently with the annual SC meetings. TC facilities will be made available in the event that not all members are able to attend in person. Further meetings will be scheduled if required.

The TCs are an extremely convenient, efficient, useful and effective tool for planning and development of the project and for reinforcing key messages to the team. The face-to-face team meetings are generally scheduled as multi-day events and attempt to address several elements of the project delivery, including both scientific as well as the administrative and financial management of the project.

Minutes are recorded for all team meetings and aim to be circulated to the team within 2 weeks. Due to the scientific and technical nature of the WP meetings, the WP leaders are responsible for preparing the agenda and minutes for the WP meetings, calling on assistance from the Project Manager if required. For all other meetings, the Project Manager will be responsible for preparing and circulating the agenda and minutes, calling on assistance from the coordinating team (Warwick) if required. The Project Manager will upload agendas, minutes and accompanying documents onto the InSPiRe intranet.

Intranet site

An intranet site will be developed for all InSPiRe team members and ISAC members only. The intranet will be managed by the Project Manager. The site will have various shared project management tools and reports; a dedicated area for sharing large documents/files within the team; meeting schedules,

agendas and minutes; useful resources and guidance documents. The InSPiRe team and ISAC are welcome to suggest and advise on the content they wish to be made available to them on the site. It is intended that the intranet will contain any key communications and documents discussed previously via email or during team meetings which will in turn will reinforce transparent communication to all.

Group emails

Group emails are the most effective way of communicating with the InSPiRe team and ISAC members. The flexibility of emails also allows the communication of targeted and relevant messages.

A detailed breakdown of internal communications required during the project is shown in Table 1.

Table 1. Summary of Internal Communications Structure (between InSPiRe team, between InSPiRe team and ISAC, between coordinating institution (Warwick) and partner financial administrators)

Category	Audience *(Who needs to know?)*	Information to be communicated *(What do they need to know?)*	Method of communication *(How will the information be communicated?)*	Frequency of communication *(How often is this information to be communicated?)*	Person(s) responsible for communication, and required actions
Plans (Work package plan, Project plan)	Project Manager InSPiRe team	Work Package Plans (to include description and duration of tasks, persons responsible, dependencies, risk assessments, and identification of linked tasks and deliverables)	Email	Every 12 months (First plan requested in June 2014)	**WP leaders:** To complete a template produced by Project Manager detailing WP plan
	InSPiRe team ISAC	Project Plan	Email InSPiRe website (intranet)	Deliverable D6.2; due August 2014 and plan to be updated after 12 months	**Project Manager:** To combine work package plans to form the overall Project Plan. To upload the Project Plan onto InSPiRe website (intranet).
Meetings (WP, SC, ISAC – TCs and face-to-face)	InSPiRe WP teams Project Manager	Work Package (WP) TC proposed meeting schedule, agendas and minutes	Email InSPiRe website (intranet)	At least every 3 months. Additional meetings to be scheduled if required.	**WP leaders:** To arrange and inform the date and time of WP meetings (Project Manager to assist as required). To prepare and circulate agenda, and prepare and aim to circulate minutes within 2 weeks of the meeting. To manage the logistics of their WP meetings. **Project Manager**: To arrange and inform of the date and time of WP2 meetings, prepare and circulate agenda, and prepare and aim to circulate minutes within 2 weeks of the meeting. To manage the logistics of the WP2 meetings. To update meeting schedule and upload agenda and minutes to InSPiRe intranet. **Warwick Team:** To assist Project Manager with scientific minutes, as required.
	InSPiRe team	Steering Committee (SC) proposed teleconference (TC) and face-to-face meeting schedule, agendas and minutes	Email InSPiRe website (intranet)	Every 3 months (TC), and annually (face-to-face)	**PI/Project Manager**: To prepare and circulate SC meeting agenda. **Project Manager:** To manage the logistics of all SC meetings (TC and face-to-face) at the coordinating institution (Warwick). To prepare and aim to circulate minutes within 2 weeks of the meeting. To update meeting schedule, and upload agenda and minutes onto the InSPiRe intranet. **WP leaders:** To manage the logistics of the annual SC meeting at their institution. This will occur once for each WP team leader throughout the duration of the project (MUW 2014, INSERM 2015, and anticipated to take place at UMG 2016 and UoW 2017) **InSPiRe team**: To assist with scientific parts of minutes as required.
	InSPiRe team ISAC	Independent Scientific Advisory Committee (ISAC) proposed meeting schedule, agendas and minutes	Email InSPiRe website (intranet) During first ISAC meeting ISAC meeting minutes	Proposed meeting schedule to be communicated at start of project, and at the first ISAC meeting. Schedule to be available on InSPiRe website (intranet)	**PI/Project Manager**: To prepare and circulate ISAC meeting agenda. **Project Manager:** To manage the logistics of the annual ISAC meeting at the coordinating institution (Warwick). To prepare and aim to circulate minutes within 2 weeks of the meeting. To update meeting schedule, and upload agenda and minutes onto the InSPiRe intranet. **WP leaders:** To manage the logistics of the annual ISAC meeting at their institution This will occur once for each WP team leader throughout the duration of the project (MUW 2014, INSERM 2015, and anticipated to take place at UMG 2016 and UoW 2017) **InSPiRe team**: To assist with scientific parts of minutes as and when required

Category	Audience *(Who needs to know?)*	Information to be communicated *(What do they need to know?)*	Method of communication *(How will the information be communicated?)*	Frequency of communication *(How often is this information to be communicated?)*	Person(s) responsible for communication, and required actions
Reports including WP progress reports, financial reports (informal to Project Manager), reports on project status and performance, scientific and financial reports to the EC (deliverable reports)	InSPiRe team	Work Package progress report templates required to update on project progress/status	Email Verbally InSPiRe website (intranet)	Once at start of project. InSPiRe SC (Kick-off meeting) Templates continuously available on InSPiRe website (intranet).	**Project Manager:** To prepare template for each Work Package and upload to InSPiRe intranet. To update templates approx every 12 months (based on information from WP Plans)
	Project Manager InSPiRe team ISAC	Work Package progress reports	Email InSPiRe website (intranet)	Every 8 weeks (Start dates will vary by WP)	**WP leaders**: To submit report to Project Manager
	InSPiRe team (particularly WP team leaders and deputy leaders) Partners financial administrators	FP7 Financial guidelines and responsibilities of partners/beneficiaries Financial reporting requirements	Email Verbally SC meeting minutes InSPiRe website (intranet)	At start of project During SC meetings (every 3 months) Guidelines and meeting minutes continuously available on InSPiRe website (intranet)	**Project Manager:** To send EC financial guidance documents to InSPiRe team and partners financial administrators, where applicable. To prepare further guidance documents and answer financial queries where applicable. To upload guidance documents onto the InSPiRe intranet. To prepare a financial reporting template (Form C template) for partners/beneficiaries in readiness for the financial reporting periods. **InSPiRe partners/beneficiaries:** To ensure that financial administrators are aware of the EC financial guidelines.
	Project Manager	Financial Report from each partner/beneficiary	Email (for Project Manager update only) Via EC Participant Portal (Formal completion of EC Form C)	Email - approximately every 6 months, starting from November 2014 Participant Portal – end of financial reporting periods 1 and 2 (31 July 2015 and 31 May 2017)*	**Partners/Partners financial administrators**: To complete DRAFT Form C template issued by Project Manager To complete the EC Form C on the Participant Portal **Project Manager:** To ensure all partners financial administrators have access to the EC Participant Portal
	InSPiRe team	Brief summary report on project status and performance (objectives)	Email InSPiRe website (intranet)	Every 6 months, starting December 2014	**Project Manager:** To produce a brief summary report, indicating spend against budget; general progress with tasks and deliverables, details of any project slippage and associated impacts; issues/risks relating to delivery of the project.
	InSPiRe team	Deliverables (inc due dates)	Verbally InSPiRe website (intranet)	During meetings, as required Continuously available on InSPiRe website (intranet)	**Project Manager:** To upload list of deliverables and due dates onto the InSPiRe website (intranet). To produce a front page template to be used for all deliverable reports. **WP leaders:** To note when deliverables are required for their WPs, and submit reports to Project Manager in readiness for submission to the EC.

External Communications Structure

External Communications will occur between the University of Warwick and the European Commission, and between the University of Warwick and the general public. A detailed breakdown of external communications required during the project is shown in Tables 2a and 2b.

Table 2a. External Communication Structure between the University of Warwick and the European Commission

Audience *(Who needs to know?)*	**Information to be communicated** *(What do they need to know?)*	**Method of communication** *(How will the information be communicated?)*	**Date of communication** *(How often is this information to be communicated?)*	**Person(s) responsible for communication, and required actions**
European Commission (Desk Officer)	Submission of deliverables: Deliverable 5.1 Deliverable 6.1 Deliverables 2.1 and 3.1 Deliverables 1.1 and 4.1 Deliverable 5.3 Deliverable 2.2 Deliverable 3.2 Deliverables 1.2 and 4.2 Deliverables 4.2 and 1.3 Deliverable 2.3 Deliverables 1.4, 2.4, 3.3, 4.3, 5.2, 5.4, 5.5, 5.6, 6.2, and 6.3	Via EC Participant Portal	 30/04/2014 (3 months) 31/08/2014 (7 months) 28/02/2015 (13 months) 31/05/2015 (16 months) 31/07/2015 (18 months) 30/11/2015 (22 months) 30/04/2016 (27 months) 31/05/2016 (28 months) 30/09/2016 (32 months) 30/11/2016 (34 months) 31/05/2017 (40 months)	**Project Manager:** To submit deliverables to the EC using the online EC Participant Portal.
European Commission (Desk Officer)	Proposed virements, Seeking approvals, Requesting extensions, Invitations to events (meetings, conferences)	Email	As required	**Project Manager**

Table 2b. External Communication Structure (via website and social media)

Audience *(Who needs to know?)*	**Information to be communicated** *(What do they need to know?)*	**Method of communication** *(How will the information be communicated?)*	**Frequency of communication** *(How often is this information to be communicated?)*	**Person(s) responsible for communication, and required actions**
General Public	Project details, project team and contact details, news, press releases.	Website (external)	Website to be created by 30/04/2014 (3 months). Website will be maintained as and when required (e.g. addition of new links, news, press releases and updates to general content)	**Project Manager**

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Deliverable Report 6.1 (Part 3):
Data Handling Policy

Data Handling Policy

1 General Principles

This data handling policy has been developed and addresses the legal issues concerning the use, management, integrity, confidentiality, preservation and sharing of research data.

The purpose of this policy is to ensure that data used through the research activities of the InSPiRe project team are approved ethically. It will also ensure that data and information used or generated during the project are stored carefully, made accessible for use and reuse as appropriate, managed over time and disposed of, according to legal, ethical, EC FP7 requirements and good practice. The plan will be kept updated to ensure continued compliance with institutional guidance and national or EU legislation.

All InSPiRe partners are required to comply with their local or institutional policies, guidelines and standards. At Warwick, all data handling and management will be in line with Warwick's own institutional policies and procedures (which also refer to relevant EU legislation). Relevant policies and procedures include:

- Research Data Management Policy
- Information Classification and Handling Procedure
- Standard Operating Procedure (SOP) 6: Ethics approvals and communications.
- Standard Operating Procedure (SOP) 15: Information Handling Part 1: Data management
- Standard Operating Procedure (SOP) 15: Information Handling Part 2: Electronic Data Security

2 Project Data

The project is concerned solely with the development of novel methodology, and software to implement these new methods. As such, the project will not involve the conducting of clinical trials, the delivery of treatment to any patients or the collection or generation of any new data from any patients or human subjects.

The project will involve the secondary analysis of data to assess the methods developed or to illustrate case-studies of the novel methodology. In all cases these will be data from clinical trials or data held in registries or available from routine clinical care databases. This includes published data (e.g. anonymised data from journals and summaries of published work, clinical trial data, case studies), and collected but unpublished data (e.g. from completed or ongoing clinical trials, non-trial data from registries and health records).

Identification of appropriate data sources will form part of the work of this project.

3 Ethical considerations

When dataset(s) have been identified, the InSPiRe team will comply with the legal and ethical requirements existing in the UK and in the countries where the research is to be conducted. In all cases the data protection laws of the relevant member states and regions will be observed.

All InSPiRe partners will comply with their local or institutional policies, guidelines and standards. At Warwick we will comply with SOP6: Ethics approvals and communications. If in doubt, the local ethics committees/institutional review boards will be consulted.

Detailed information will be obtained and provided to the EC on the source of any previously collected personal data used in the project along with explicit confirmation that ethical approval have been obtained to cover their use in this project. The source of all data and this explicit confirmation will be documented prior to commencement of any analysis of the data. If any personal data are to be used beyond the scope of the current project, additional explicit consent for their use will be required and obtained.

Any personal data used in the project will be coded so that no personal identifiable data will be used in the project or accessed by any member of the project team as part of their work on this project.

We will acquire copies of Ethics approvals when relevant from the partner and host country as required. These approvals will be held in a Project Master file, with copies sent on to the EU. The Master file will be managed by the Warwick Medical School Research Ethics and Governance Manager and the InSPiRe Project Manager, with oversight from the project coordinator, and will be kept in a locked cabinet in a secure room at University of Warwick.

A report on ethical and data protection issues will be included in the project periodic reports.

4 Data Management

This section outlines the plan for the storage, protection, sharing, transfer, retention and destruction of information and data throughout the duration of the InSPiRe project. InSPiRe team members will ensure they are familiar with this plan prior to handling or analysis of any personal/sensitive personal data.

Personal data means data which relate to a living individual who can be identified:

a. from those data, or
b. from those data and other information which is in the possession of, or is likely to come into the possession of, the data controller,

and includes any expression of opinion about the individual and any indication of the intentions of the data controller or any other person in respect of the individual.

Sensitive personal data means personal data consisting of information as to:

a. the racial or ethnic origin of the data subject,
b. his political opinions,
c. his religious beliefs or other beliefs of a similar nature,
d. whether he is a member of a trade union (within the meaning of the Trade Union and Labour Relations (Consolidation) Act 1992),
e. his physical or mental health or condition,
f. his sexual life,
g. the commission or alleged commission by him of any offence, or
h. any proceedings for any offence committed or alleged to have been committed by him, the disposal of such proceedings or the sentence of any court in such proceedings.

4.1 Data Storage and Protection

All data will be held securely in compliance with EC and member state guidance and legislation on information and personal/sensitive personal data security. In addition, all InSPiRe partners will comply with their local or institutional policies, guidelines and standards. At Warwick we will comply with the Warwick University Information Classification and Handling Procedure, together with SOP 15, Information Handling Part 2: Electronic Data Security.

The data protection procedures that will be implemented in the project will be detailed. These will demonstrate compliance with institutional procedures and the national, regional and European legal framework.

Confidentiality of data will be maintained and respected throughout and after the duration of the project. Staff will comply with the Data Protection Act 1998. Any personal data will be held in accordance with the Act. The eight principles of the Data Protection Act states that personal information should be:

- **Fairly and lawfully processed** (in particular that the individual whose information it is has consented to the processing of his/her personal information)
- **Processed for limited purposes** (only for the purposes for which it was originally supplied)
- **Adequate, relevant and not excessive**
- **Accurate and up to date**
- **Not kept longer than is necessary** (personal information shall be retained only for as long as is required to fulfil the purposes of this project. Beyond this point it shall be securely destroyed.)
- **Processed in accordance with the data subjects' rights**
- **Secure** (from the point at which personal information is received until the point at which it is destroyed, such information will be processed securely. We will ensure that we have appropriate mechanisms in place to ensure adequate security for the storage and

transmission of all electronic and paper records containing personal information, particularly more sensitive personal information.)

- **Not transferred to a country or a territory outside the European Economic Area (EEA) unless that country or territory ensures an adequate level of protection**

Disclosed clinical data will be anonymised at all times. Sensitive data will never be sent electronically. Where possible, trial participants will only be identified by their allocated individual trial number and in all cases the use of patient identifiable sensitive data will be prohibited.

The InSPiRe Project Coordinator, Project Manager and relevant work package leader will identify those members of the project team who need access to project data and data will be accessible only to these people. These members of the project team will be made aware of relevant documents relating to the management of personal data.

All members of the project team that are to handle personal data will confirm they are up to date with relevant mandatory training at their respective Institution.

Each InSPiRe team member is responsible for taking reasonable steps to ensure there is no unauthorised access to systems they are responsible for. When working on sensitive information it is important to ensure that the data can only be read by authorised persons.

Users shall create strong passwords for their user accounts and must not write down or disclose these to anybody. Passwords should not: use any variation of a login name or a full name; use a dictionary word, even if numbers or punctuation are added to it; use proper names of any kind; use any continuous line of letters or numbers on the keyboard e.g. qwerty or asdfg. Passwords should have combinations of upper and lowercase characters, numbers and non-alphanumeric characters. Staff must never reply to any electronic communication that requests a user name or password.

Adequate antivirus software will be installed on all computers.

4.2 Sharing and Transfer of Electronic Personal and Sensitive Data

Any personal/sensitive personal data will be transferred in accordance with relevant EC and member state legislation such as, in the UK, the Data Protection Act 1998. In addition, all InSPiRe partners will comply with their local and institutional guidelines and/or procedures. At Warwick we will comply with the Warwick University Information Classification and Handling Procedure, together with SOP 15, Information Handling Part 2: Electronic Data Security.

In Particular:

- Special care will be taken when moving clinical data from a secure storage location. All portable media (e.g. USB drives, CD/DVD, laptops etc) will use a 256 bit Advanced Encryption

Standard (AES-256) algorithm. Portable media will only be used as a temporary storage device and clinical data will be securely deleted once the portable device is no longer required.

- Data sent electronically will be encrypted using AES-256 and sent via a secure connection e.g. Virtual Private Network (VPN), Secure Shell (SSH), File Transfer Protocol Secure (FTPS). Any data received electronic will be moved to a secure storage location or be securely deleted.

4.3 Retention and Disposal of Data

At the end of the research project all research project data will be reviewed by the project coordinator, project manager and relevant work package leader to determine what needs to be retained to meet contractual, legal or project record-keeping requirements. Any data which does not need to be retained will be permanently destroyed. For electronic data and information, advice and instructions will be sought

If any personal data are to be used beyond the scope of the current project, additional explicit consent for their use will be required and obtained.