

## Announcement of Opportunity

# Life Science Research Using the Spaceflight Analogue “Bed Rest”

AO-2009-BR



Image: CNES/S. Levin



Image : ESA/Vista S.T.I.

**Letters of Intent due: 15 June 2009**  
**Proposal Workshop: 23 June 2009**  
**Proposal Deadline: 14 September 2009**

## Summary of the Announcement of Opportunity

- ESA Announces an Opportunity to propose Life Science Research Using the Spaceflight Analogue “Bed Rest”
- Proposals of new countermeasures are NOT part of this Announcement
- Proposals should address physiological areas, which could be affected by bed rest and countermeasure use.
- Two bed rest studies are targeted. Both will be medium duration, i.e. with a 21 day head down tilt period.
- Submission of Letter of Intent and proposals will be done this time electronically. The proposal must use the template from the AO website. Submission of Lol and proposal will be via the web
  - For Lol: <http://www.esf.org/loi/bedrest>
  - For proposals: <http://www.esf.org/bedrest>
- Contact for questions related to this research announcement:  
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Announcement specific email address: [bedrest@esa.int](mailto:bedrest@esa.int)
- For technical questions related to the submission website please contact [EsaPeerReview@esf.org](mailto:EsaPeerReview@esf.org)
- Deadlines:
  - Letters of Intent due: 15 June 2009
  - Proposal Workshop: 23 June 2009
  - Proposal Deadline: 14 September 2009

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## 1 Introduction

When exposed to weightlessness in space, the human body undergoes a variety of adaptations, incl. bone mass loss, muscle mass loss, fluid shift, cardiovascular deconditioning etc. These changes are problematic when returning to a gravity environment, or potentially in emergency situations.

Different exercises and other measures (referred to as “countermeasures” in the space context) are employed in an attempt to limit these adaptations. However the currently employed suite of countermeasures encompasses the use of large equipment and requires a significant amount of time, and yet it has been shown that these measures do not fully prevent the changes.

Continuous exposure of healthy volunteers to a  $-6^{\circ}$  head-down tilt position while resting in beds has been shown to be a good model for many of the physiological changes that take place in spaceflight. In addition to providing the opportunity to study the physiological mechanisms, these Bed Rest (BR) studies also allow to test the effectiveness of countermeasures and protocols. Obviously, the results of these BR studies are very relevant also for e.g. clinical environments, where patients also undergo bed rest for a variety of different reasons.

## 2 ESA’s Approach to Bed Rest Studies

ESA has been conducting a very successful BR study programme since many years. In 2005, based on the experience gained, and taking into account some new factors (need for structured countermeasure evaluation in preparation of human space exploration, need for faster availability of core study results etc.), the organisational approach was modified.

Now, the priorities for the countermeasures protocols to be evaluated are defined for a few years ahead, i.e. for multiple BR studies. The protocols for these studies are defined by expert groups that have proven experience for that type of countermeasure.

Also, a standard set of “gold standard” measurements, called Bed rest Core Data (BCD) is collected in each ESA BR, so that the evaluation of countermeasure effectiveness between different studies is possible.

On top of this, an Announcement of Opportunity (AO, like the one you are currently reading) is published for a given set of BR studies. Experiments selected through these AOs are distributed to the best suited planned BR study, complementing the strategic countermeasure evaluation with high-quality fundamental research.

As the priorities stated in the first version of the ESA BR strategy either have been, or are in the process of being addressed, recently there was an update of the ESA BR strategy. This update is based (like the first version) on a user consultation and a workshop. Details of the update can be found in Annex 1.

## **2.1 Bed Rest Core Data (BCD)**

BCD are defined for the main physiological areas incl. bone, muscle, cardiovascular system, nutritional status etc. A detailed list of the BCD measures relevant for this AO can be found in Annex 2.

BCD will be analysed by the expert groups that defined the countermeasure protocol to derive the countermeasure effectiveness.

Data from BCD measurements is in principle also available for research projects, if the BCD has been requested in the proposal. In such a case priority for publication of a BCD measurement will usually be given to the selected experiment (within the limits of the general ESA BR data approach, see section 6).

## **2.2 Bed Rest Standardisation**

When initiating the strategic approach for BR it became clear that one of the prerequisites to be successful in this approach was the standardisation of BR study conditions. To this end, an ESA standardisation document was produced, that details many aspects around BR studies, incl. study management and project communication, study protocol, volunteer selection, volunteer rules, (para) medical care, nutrition standardization, handling of biological samples, data management and a description of Standard Operating Procedures for many activities. Some of these standards, e.g. inclusion/exclusion criteria for test subjects, only represent the minimum required to allow some comparability between studies. If your experiment requires general study conditions that are very specific (e.g. specific range of  $VO_2$ max etc.) this should be stated in the proposal and will be discussed at the Investigator Working Group meeting of the relevant bed rest study.

## **3 Bed Rest Studies Targeted by this AO**

This AO is soliciting proposals to be implemented in two medium duration BR studies in male subjects. Medium duration BR studies are defined in the ESA standardisation as having a baseline data collection period of 7 days, a head-down tilt period of 21 days, followed by a recovery period of again 7 days.

The currently foreseen countermeasure protocols that will be tested are

- The combination of artificial gravity (AG, through centrifugation on a short arm centrifuge) and resistive vibration exercise (RVE) in one study. This will probably be done in 3 campaigns.
- The combination of exercise with a nutritional supplementation (whey protein and an alkalisng agent), likely also with 3 campaigns.

The detailed protocols will be elaborated at a later point in time, and some modifications may yet occur. However for the proposals in response to this AO, these two countermeasure protocols should be regarded as the baseline. Planned timeframe for implementation of these two BR studies is 2011/2012.

## 4 Proposals solicited by this AO

Proposals should address physiological areas, which could be affected by bed rest and countermeasure use. Any type of research field can be addressed, for example:

- Integrative physiology
- Bone
- Muscle
- Nutrition and metabolism
- Neurology
- Cardio-vascular system
- Rehabilitation Medicine
- Pharmacology
- Gastro-intestinal, splenic, renal, hepatic, and pancreatic function
- Immunology
- Endocrinology
- Others

Investigations into acute effects of countermeasure applications (e.g. cardiovascular reflexes during short-arm centrifugation etc.) are also welcome.

Please bear in mind that during the bed rest phase no testing can be performed in a sitting or standing position. Tests requiring a degree of physical activity should be kept to an absolute minimum or be avoided during the bed rest phase. Instead, such testing should be scheduled before and after bed rest. In this way countermeasure effects caused by testing procedures are minimised. However, if compelling scientific reasons exist, a trade-off will be made assessing the value of the procedure from a selected proposal in the context of the specific study.

## 5 Proposal Evaluation and Selection Procedures

### 5.1 Scientific Merit Review

Programme-compliant proposals submitted in response to this AO will undergo a scientific merit (peer) review. Only those proposals most highly rated in the scientific merit review process will undergo the additional review for feasibility.

This time, the scientific merit review will be outsourced to the European Science Foundation (ESF) under ESA contract. However, the principles outlined below will still strictly apply and the peer review process will be closely monitored by ESA and representatives of the Advisory Groups.

The technical evaluation of the projects that are positively evaluated by the scientific panels will still be performed by ESA.

All of the following criteria will be used in determining the merit score:

**Significance:** Does the study address an important problem? If the aims of the application are achieved, how will scientific knowledge or technology be advanced? What will be the effect of these studies on the concepts, methods, or products that drive this field?

**Approach:** Are the theoretical framework, experimental design, data analysis and interpretation methods adequately developed, well integrated, and appropriate to the aims of the project? Is the proposal hypothesis-driven? Is the proposed approach likely to yield the desired results? Does the applicant acknowledge potential problem areas?

**Innovation:** Does the project employ novel concepts, approaches, or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

**Personnel:** Are the scientific personnel appropriately trained and well suited to carry out this work? Is the evidence of the personnel's productivity satisfactory? Are the functions and responsibilities of the team members adequately described and appropriate? Does the project employ useful collaborative arrangements?

**Environment:** Does the institutional environment, in which the work will be performed, contribute to the probability of success?

In the review, each proposal will receive a scientific merit score between 0 and 100 points. As a result of the scoring the proposals will receive one of the following marks:

- Outstanding 100 - 91 points
- Excellent 90 - 81 points
- Very Good 80 - 71 points
- Good to Fair 70 - 46 points
- Unacceptable 45 - 0 points

The scoring will be weighted according to the 5 sub-criteria:

- Significance 30%
- Approach 25%
- Innovation 20%
- Personnel 15%
- Environment 10%

The peer board will also evaluate the proposal's relevance to space- and/or bed rest. Again, scores between 0 – 100 will be given, resulting in a second mark.

## **5.2 Evaluation of Feasibility**

For the selected proposals following the peer review (the most highly rated proposals), a second review level will determine the feasibility of the proposed protocols. This review will also determine in which bed rest studies the proposed experiments best fit. Thereafter an integrated protocol with the BCD measurements and the protocols from the selected experiments will have to be integrated in a common overall protocol before being submitted to the institutional review board for final acceptance. This process is typically done by Investigator Working Group meetings. The overall efficiency of any multidisciplinary bed rest study does depend on how many different highly scored proposals can be accommodated in this final integrated study protocol. The assessment of feasibility refers to the extent as well as the adaptability of the proposed work, and how well it can be integrated into an overall study scheme. It will be in favour of the research proposal, which is being evaluated, if it utilises the measurements of BCD instead of proposing similar redundant protocols. Indeed, BCD will be performed in any case independent of any specific experiment selected. Proposed measurements should not interfere with or disturb the foreseen BCD. Flexibility in scheduling the additionally required measurements will also be of advantage. The tests required in addition to the BCD should ideally have a high “value for effort ratio”, i.e. yield a maximum amount of valuable scientific data with as little technical effort and time constraints as possible.

The marking on technical feasibility shall cover the following sub-criteria:

- Functional requirements
- Resource requirements
- Safety

The following scoring scheme will be applied:

|       | Can be implemented immediately | Feasible with minor adaptations | Some issues to be resolved | Major concerns | Not feasible |
|-------|--------------------------------|---------------------------------|----------------------------|----------------|--------------|
| Score | A                              | B                               | C                          | D              | E            |

Those proposals receiving one or more ‘E’s or two or more ‘D’s in any of the above sub-criteria shall be deemed to be not feasible and will therefore be proposed to be not approved.

### **5.3 Development of a Selection Recommendation**

A selection recommendation will be developed based on the merit review, space/bed rest relevance and feasibility as described above. Deficiencies in any one of these factors may prevent selection of a proposal. The development of selection recommendations is the responsibility of ESA supported by its advisory bodies.

ESA reserves the right to select only a part of a Science Team Coordinator’s project if this portion is still of high scientific merit. The applicant will be given the choice to accept or decline such a partial opportunity. If two or more proposals address similar problems and/or adopt similar approaches, ESA may request that the STCs consolidate specific parts of their projects into a single project and work as one team.

The selected experiments will be accommodated as soon as possible in the upcoming ESA bed rests described above. An experiment may be implemented in more than one bed rest study if needed, depending for example on the type of countermeasure, the duration of a bed rest or the number of subjects required.

## 6 Data Rights

### 6.1 General

Data resulting from the experiments in the context of this AO will be analysed and exploited in line with applicable general data policies of the Agency. Final results of the study shall be made available by the scientific teams to the scientific community through publication in appropriate journals or other established channels as soon as practicable and consistent with good scientific practice. In the event such reports or publications are copyrighted, ESA shall have a royalty-free right under the copyright to reproduce, distribute, and use such copyrighted work for their purposes. Specific and Additional Data Regulations for Bed Rest Studies

### 6.2 Data Classification

Three types of experiment data are identified:

**Category 1** data will be obtained and processed under the responsibility of a Science Team Coordinator for the experiment protocol. Data not requested by any other STC may be used exclusively by the STC for scientific purposes. For data requested by more than one STC, each STC must agree before the study starts as to the conditions for the data usage for scientific purposes. This category of data shall be referred to as “STC proprietary data.” The STC proprietary data may be used by the sponsoring agencies for internal purposes. The sponsoring agencies agree that this data will not be made public for 1 year after the completion of the study’s clinical phase (last point of data collection in the ambulatory recovery period following the bed rest).

**Category 2** data comprise BCD, as defined and owned by ESA. STCs can apply, and are even encouraged to use BCD. ESA, in consultation with the bed rest steering committee, will decide on the first publication rights for BCD. Scientific merit of the respective proposal and thematic relevance will be the key factors influencing the ranking.

There will also be common clinical data (**Category 3**) for usage by all STCs/STMs. This will be distributed to STCs.

Category 2 and 3 data will be stored in a future European Microgravity Database for Clinical Research (EMD-CR). It is compulsory that the respective STC will make Category 1 data available to ESA for any use 12 months after completion of the study’s clinical phase.

In case follow-up points are required, long after the bed rest per se, for publication, a STC can apply for extension of the one-year exclusive publication period by submitting a scientific report in the format of a manuscript 1 year after the completion of the study’s clinical phase.

### **6.3 Data Access**

A STC can access proprietary data from other STCs participating in the study through a written data sharing agreement (signed by involved STCs). ESA will ensure that a data-sharing plan among the participating STCs is established prior to the beginning of the respective bed rest study.

All STC proprietary data and BCD will be treated as medical confidential information by the participants and ESA.

### **6.4 The Erasmus Experiment Archive (EEA)**

The EEA is an ESA service to the international scientific community. Abstracts, from all European microgravity experiments performed to date are collected in this database. Experimenters sponsored by ESA have the obligation to provide these abstracts themselves. Special emphasis is placed on the completeness of the list of references of articles where the experiment results can be found.

The database includes a full-text search capability to retrieve information on experiments in a certain discipline, subject, mission, or by investigator name. The EEA covers both physical and life sciences, and can be found at the following URL:

<http://spaceflight.esa.int/eea/>

This database includes also a large number of pictures, as well as video sequences documenting experiment abstracts.

Scientists in Europe who have performed experiments, be it in orbiting or ground-based facilities (drop-tube, drop-tower, parabolic flights, sounding rockets, Foton capsules, the Space Shuttle or the ISS), are urged to either provide an abstract on each of their experiments, or to provide information enabling the updating of their existing abstracts, in particular the list of articles published.

An abstract features the following contents:

- Mission Name and Date
- Team Members and Affiliations
- References
- Processing facility
- Experiment Objectives
- Experiment Procedure and Results
- Attachments

Please e-mail your new abstracts (in attachment) or the updated information for already existing abstracts to the [EEA Curator](#).



## **6.5 Acknowledgement**

Any publication on the results generated during bed rest studies solicited in this AO must acknowledge ESA's sponsorship of the study.

## **6.6 Support of Education and Outreach**

The activities covered in this AO provide an opportunity for ESA to enhance and broaden the public's understanding and appreciation of research facilitated by ESA. Therefore the investigators of selected experiments are expected to promote and communicate their experiments to a wide audience (general public, colleagues, involvement of students) and to support ESA in the event of organised press conferences, educational events, publications etc.

## **7 Proposal Preparation Guide**

### **7.1 Contact**

For questions related to this research announcement please contact

ESA/ESTEC/HSF-USL

Oliver Angerer

Tel. +31 71 565 3728

Announcement specific email address: [bedrest@esa.int](mailto:bedrest@esa.int)

For technical questions related to the submission website please contact

[EsaPeerReview@esf.org](mailto:EsaPeerReview@esf.org)

It is planned to organise a proposal workshop in connection to this research announcement on 23rd of June 2009. The workshop will take place at ESTEC, Keplerlaan 1, Noordwijk, The Netherlands. This will be an opportunity to clarify potential questions and gather contacts for cooperative research projects. To facilitate logistics and planning, please indicate your intention of participation to the proposal workshop when you submit the Letter of Intent.

### **7.2 Time Schedule**

Letters of Intent due: 15 June 2009

Proposal Workshop: 23 June 2009

Proposal Deadline: 14 September 2009

### **7.3 Letters of Intent**

To facilitate timely proposal processing (e.g. organisation of peer review), potential investigators are requested to confirm their plans to submit a proposal in response to this announcement. The Letter of Intent is not binding. A letter of intent (LoI) is requested by 15 June 2009. LoIs should be submitted online through the European Science Foundation (ESF) web site. The online submission form can be found at

<http://www.esf.org/loi/bedrest>

The LoI online form requests the following information:

- Science Team Coordinator's (STC) contact details and institution
- Science Team Members' (STM) contact details and institutions
- Project Title, acronym
- Project Summary
- Keywords and research area(s)

## **7.4 Proposals and Funding**

Costs related to access to the bed rest facility and subjects are covered by ESA. However, ESA does not financially support the work of selected experimenters. Any additional expenses related to the proposed work of an experimenter, including costs for travel and subsistence, are considered investigator-related costs, which are not sponsored by ESA. Co-funding from national agencies / organisations, universities, or other institutions is required to cover investigator-related costs. ESA strongly advises STC/STMs to submit their proposal to their national bodies (see Annex 3 for national contact points) in parallel with their application in response to this AO, in order to commence applying for national funding as early as possible. If the proposed experiment is selected a proof of appropriate funding is mandatory in order to commence implementation of the project.

The proposal must be written in the format described below, and using the proposal template provided on the ESA BR AO website. This format is not intended to increase the “paper work” but should be considered as a useful guideline, which will permit a fair and standardized evaluation of the proposals.

## **7.5 Proposal Submission**

Proposals must be submitted online through the European Science Foundation (ESF) web site by 14 September 2009. The online submission website can be found at

<http://www.esf.org/bedrest>

The online submission process includes several steps.

Proposers will be asked to fill in online the names and full contact details of the Science Team Coordinator and all Science Team Members, specifying the members’ institutional affiliations. Mandatory fields are specified in the online form. A signature version of this form will not be requested. Furthermore proposers must provide an abstract and proposal acronym, and specify relevant keywords and research areas. The information requested in this part of the form is essential to the review of the proposal.

The information submitted will then be saved by the system. Proposers will then be required to upload their proposal. The saved information and the uploaded proposal will then be automatically merged and forwarded to proposers. This document, stored in the ESF database, will represent the reference document for future queries.

All proposals to be uploaded must be contained in one single and non-protected pdf document, not exceeding 8MB in size, using the proposal

template provided on the ESA BR AO website, covering the following material, in this order:

- Project Description
- Management Approach
- Biographical Sketches
- Supporting Budgetary Information
- Ethics & Safety
- Experiment Data Sheet

### 7.5.1 Project Description

The length of the Project Description section of the proposal should not exceed twenty (20) pages using regular (12 point) type. The proposal should contain sufficient detail to enable a reviewer to make informed judgments about the overall merit of the proposed research and the probability that the investigators will be able to accomplish their stated objectives. The proposal should clearly indicate the relationship between the proposed work and the research emphasis defined in this Announcement of Opportunity. The development of a clear hypothesis, along with the available data evidence, should be emphasized in this section.

### 7.5.2 Management Approach

Each proposal must specify a single Scientific Team Coordinator, who is responsible for carrying out the proposed project and coordinating the work of other personnel involved in the project. The scientific institution for which the coordinator of a proposal is working must be located in one of the ESA member or associated member states that contribute to the ELIPS programme: **Austria, Belgium, Canada, Czech Republic, Denmark, France, Germany, Greece, Ireland, Italy, The Netherlands, Norway, Spain, Sweden, Switzerland**. Scientists from ESA Member States that do not contribute to the ELIPS Programme (presently Finland, Portugal, Luxemburg and the United Kingdom), and scientists from other European countries having a cooperation agreement with ESA, are encouraged to enquire with their national space organisation about the conditions for their participation in proposals to ESA.

In proposals that designate several senior professionals as key participants in the research project, the management approach section should define the roles and responsibilities of each participant, and note the proportion of each individual's time to be devoted to the proposed research activity. The proposal should state clearly and unambiguously whether the key personnel have reviewed the proposal and endorsed their participation.

Despite the fact that cooperative research proposals are favoured, big clusters of research proposals are not welcome because of the difficulty for



the peer reviewers to make their judgement and later on the difficulty of implementation with the other selected protocols.

The STC is the main ESA point of contact for a team and must participate in the conduct of the research. He/she is responsible for direct supervision of the work and efficient communication among STMs.

### **7.5.3 Biographical Sketches**

A short curriculum vitae (not exceeding 3 pages) of the Science Team Coordinator, which includes her or his current position, title and educational background, list of principal publications (up to 20), and any exceptional qualifications should be included. Give similar biographical information on other senior professional personnel who will be directly associated with the project (STM). Universities should list students or other assistance involved, together with information as to their level of academic achievements. Any special industry-university cooperative arrangements should be described.

### **7.5.4 Supporting Budgetary Information**

Please describe briefly the status of co-funding availability and/or applications.

### **7.5.5 Ethics & Safety**

A statement from the proposal's institution is required which states that the proposed work will meet all local human subject requirements if applicable. A letter signed by the chairperson of the local Institutional Review Board (IRB) regarding approval of the experimental protocol and using human subjects, should be included with the proposal. In addition, the proposal must be compliant with applicable European laws and guidelines for human biomedical research. If due to the timing of IRB meetings a final approval letter should not be available by the proposal submission deadline, the ethics approval application status should be described. In those cases, the final approval letter needs to be provided after the deadline, in order for the experiment to be considered for implementation.

Safety hazards and assessments, including a description of possible hazardous situations for the test subjects, must be provided.

### **7.5.6 Experiment Data Sheet**

Please fill the details of your experimental protocol in the Experiment Data Sheet form that is part of the Proposal template.

## **Annex 1: Update of ESA's Bed Rest Strategy**

### ***Background***

ESA has been conducting a very successful bed rest (BR) study programme since many years. In 2005, based on the experience gained, and taking into account some new factors (need for structured countermeasure evaluation for human exploration preparation, need for faster availability of core study results etc.), the organisational approach was modified. Instead of organising individual BR studies, each with a dedicated Announcement of Opportunity (AO), a more strategic approach was chosen, with a definition of priorities for the countermeasures to be evaluated spanning several years, and a general bed rest AO, from which selected experiments would be distributed to the best suited studies. The countermeasure priorities were developed with the aid of a call for ideas and a follow-on workshop. Also discussed at the workshop were important general issues enabling the strategy, including standardisation of bed rest conditions and core measurements, study durations, gender aspects and control groups.

In practice, this first version of the ESA BR strategy was further refined to match the available budget in the ELIPS-2 programme phase.

Since the priorities of the first ESA BR strategy either have been, or are in the process of being addressed, the time was deemed right to update the strategy.

### ***Process***

A user consultation was published on January 14, 2009, with a deadline of February 16, 2009. Altogether 32 contributions were received. Based on the contributions participants were selected and invited for a two day workshop which took place at ESTEC on April 8+9, 2009.

### ***Workshop***

The workshop had four main sections. After an introduction and status update of ESA BR studies, a discussion on general BR characteristics was conducted. This was followed by a discussion of the received contributions, including selected detailed presentations ranging from countermeasure ideas/concepts, to prototypes and first validation results. Finally the concrete priorities for the next studies were discussed.

Main outcomes of the discussion:

- The need for proper control groups included in each study was reconfirmed.
- The usefulness of long-duration BR studies, defined with a 60 day head-down-tilt (HDT) period, was extensively discussed. One of the main justifications for this duration is the ability to observe structural changes especially in bone directly (instead of relying on indirect biomarkers). However limitations of current imaging techniques combined with positive experiences with bone markers may reduce the

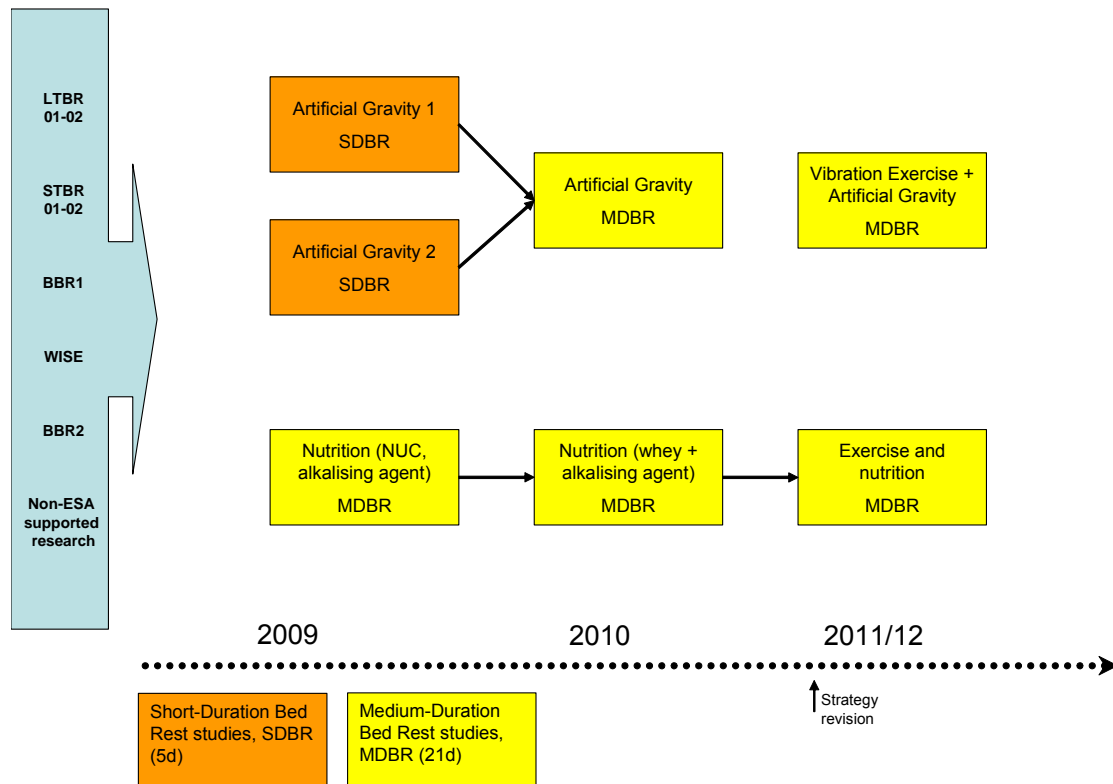
need for long-duration studies. Unfortunately no definite conclusion of this discussion could be reached. For the moment long-duration studies will remain a theoretical option, though the next studies will not go beyond medium duration (21 days HDT).

- Some discussion centred on the metabolic changes during BR. In light of recent results it appears desirable that the energy balance should be neutral, i.e. fat mass remain constant during BR. Today this is challenging to achieve if exercise is part of the protocol. Measurements will be added to one of ESA's upcoming BR studies in order to develop/validate this approach.
- It was recommended to characterise and use post-BR recovery periods more than to date: Even some testing of countermeasures and rehabilitation protocols may be possible in that period.
- Operational aspects should be taken into account when characterising and judging the usefulness of countermeasures. A specific example was that the application of vibration in conjunction with extra-vehicular activities may increase the risk of air bubble formation in the blood stream. More generally this also includes the fact, that mass, volume and energy consumption of equipment, and time requirements of protocols need to be minimised.
- It was mentioned that for some physiological systems fairly effective and proven countermeasures exist (e.g. to maintain muscle mass). Often, however, they lack effectiveness on some specific, connected aspect (e.g. balance, proprioception, neuromuscular control). One issue that was especially highlighted was the fact that stabiliser muscles of the body so far have hardly been considered in countermeasure developments. Stabiliser muscles are not sufficiently activated by the usual exercise devices, yet play a fundamental role for e.g. balance and proprioception. In light of this discussion, it was concluded to form a topical team on this topic.
- More extensive use of metabolic markers for changes in different physiological systems was seen as helpful and necessary in BR. A topical team will further develop this topic.
- Many of the countermeasure concepts that were presented seemed interesting, however lacked maturity to be considered for inclusion in a BR study at this point in time. For some of the concepts, though, additional validation (e.g. training studies) will be performed in the near future. Therefore it was concluded that at this meeting only priorities for the next two immediate bed rest studies should be fixed. Then, in one or two years, a new evaluation should be performed, taking into account the data accumulated in the meantime.
- The countermeasure concepts to be evaluated in the next two BR studies will be
  - The combination of resistive vibration exercise with artificial gravity and
  - The combination of nutritional supplementation (whey protein and alkalising compound) with exercise.

The detailed protocols will be defined by dedicated expert groups, assembled by ESA with support by the ESA Bed Rest Steering Committee, similar to the approach practiced for the BR studies stemming from the first version of the

ESA BR strategy. Fundamental research will be solicited with an upcoming AO, and selected experiments distributed to the suitable study.

### Updated Roadmap



## Annex 2: Bed Rest Core Data (BCD) and Data Collection Sessions

The table represents the list of BCD with data collection sessions that are planned to be implemented during Medium-Term Bedrest Studies (MTBR).

| BCD  | Data Collection Session                    |
|--|--|
| <b>Cardiovascular</b>  |  |
| Plasma volume  | BDC-5†,*, BDC-4*, R+0                      |
| Tilt Test + LBNP   | BDC-4†,*, BDC-2, R+0                       |
| VO2max   | BDC-5, R+2 (R+0 or R+1 if possible)        |
| <b>Muscle performance</b>  |  |
| Isometric MVC  | BDC-5*, BDC-1*, R+0, R+5*                  |
| Muscle fatigue test  | BDC-5*, BDC-1*, R+0, R+5*                  |
| <b>Nutrition</b>   |  |
| Bodyweight   | Daily                                      |
| DEXA for body composition  | BDC-5*, R+2                                |
| <b>Bone</b>  |  |
| Urinary DPD  | BDC-6*, HTD20, R+14†, R+28†                |
| Urinary NTX & CTX  | BDC-6*, HTD20, R+14†, R+28†                |
| Serum BAP & PINP   | BDC-6*, HTD20, R+14†, R+28†                |
| pQCT   | BDC-6*, HTD20, R+14†, R+28†                |
| <b>Neuro-vestibular</b>  |  |
| MHQ  | BDC-1*                                     |
| DGI  | BDC-2*, R+0, R+3                           |
| Posturography  | BDC-2*, R+0, R+3                           |
| <b>Psychology</b>  |  |
| Log of critical incidents  | when applicable                            |
| POMS   | BDC-7, BDC-3, HDT10, HDT20, R+2, R+7       |
| PANAS  | BDC-7, BDC-3, HDT7, HDT14, HDT,21 R+2, R+7 |
| Sleep Assessment   | BDC-7, BDC-3, HDT7, HDT14, HDT,21 R+2, R+7 |
| GHQ  | BDC-7, BDC-3, HDT7, HDT14, HDT,21 R+2, R+7 |
| Questions related to acceptability of the applied countermeasure | When relevant                              |

† Familiarisation session

BDC-: Before bed rest

R+: After bed rest

MVC: Maximal Voluntary Contraction

BAP, PINP: Bone formation markers

DGI: Dynamic Gait Index

PANAS: Positive and Negative Affect Schedule

\* Flexible date, ± 2 days

HDT: During bed rest

LBNP: Lower Body Negative Pressure

DPD, NTX, CTX: Bone resorption markers

MHQ: Motion History Questionnaire

POMS: Profile of Mood State

GHQ: General Health Questionnaire



## Annex 3: National Points of Contact

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