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(NASA-CR-155170) INTEGRATED STUDY PLAN FOR  
SPACE BIOPROCESSING (PHASE I) (ECON, Inc.,  
Princeton, N. J.) 11 p HC A02/MF A01

N77-33221

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INTEGRATED STUDY PLAN  
FOR SPACE BIOPROCESSING  
(PHASE I)

Contract NASW-3047

Work Order No. 5



15 May 1977

## INTEGRATED STUDY PLAN FOR SPACE BIOPROCESSING

### 1.0 Approach

The objective of this study is to apply current economic evaluation and analytical techniques to decision problems faced by the space bioprocessing program. Specifically, this study will enable NASA decision makers to choose the candidate substances, after ranking them according to their potential economic benefit. Later phases will focus on program analysis, where the relative risks and benefits will be analyzed in a decision tree analysis in order to allow NASA to determine the proper mix of projects to undertake in the STS program--projects with high risk and low risk, as well as high potential payoff and low potential payoff.

Our approach to the planning of this project is based upon two years of specific experience in the analysis of the economics of space materials processing and consists of work to be completed in three separate phases.

Phase I will be completed under this contract and is aimed at determining the appropriate evaluation technique necessary to obtain measures of the potential economic benefits which may occur as the result of the pursuit of various space bioprocessing endeavors. During this phase, ECON will also review the treatment of each disease which would be impacted by a successful outcome of space bioprocessing and specify data and other input needs for each candidate substance. Phases II and III, to be performed in subsequent years, will consist of actual data collection for benefit evaluation, and program analysis and evaluation, respectively. Each phase is described in more detail below.

## 2.0 Study Data Base

The variables of the data base will be specified during the current phase, while actual data collection will take place during the following year, in Phase II. The input factors will be determined from the evaluation technique which is selected and the specific diseases and treatments involved. Our previous experience with the benefit analysis of space bioprocessing indicates that the data base is likely to include the following factors:

- Number of persons annually afflicted with diseases for which space processing can have an impact
- Number of persons entering each treatment state or change in number of persons that will enter the treatment state
- Costs associated with each treatment or recovery state
- Earnings per person for each disease and treatment state
- Probabilities of a person entering various treatment, recovery or death states (usually from epidemiology statistics)
- Potential efficacy of new pharmaceutical products or treatment techniques based on assumed successful outcome of space processing of candidate pharmaceutical substances
- Costs of comparative production techniques.

It is important to realize that the development of the data base, like the evolution to the study, is a step-by-step process with each succeeding procedure resulting from and being consistent with the results of the previous work. This approach is key to maintaining the flexibility necessary to assure that a study of this scope can be modified to fit NASA's needs precisely as they develop over the study period. A description of the specific tasks of each phase follows.

## 2.1 Phase I--General Methodology and Data Specification

The purpose of Phase I is to determine the appropriate evaluation technique necessary to obtain measures of the potential economic benefits which may occur as the result of the successful pursuit of various space bioprocessing endeavors. In addition to selecting the appropriate evaluation technique, ECON will specify the specific data and other input needs for each of the space processing candidate substances after a systematic review of the treatment of each disease that would be impacted by a successful outcome of space processing of biological materials. The specific tasks in Phase I are:

2.1.1. In Task 1 ECON will evaluate currently utilized techniques for health program benefit evaluation, including the Markov process technique utilized by ECON for a NASA Headquarters project on the economics of space processing.\* ECON will perform a literature review, including a survey of government documents on the subject of health treatment systems economic benefit evaluation techniques. Concurrent with the review of benefit evaluation methodologies, ECON will classify the candidate substances or processes according to how economic benefits would be derived. For example, benefit classification categories such as reduced mortality, increased longevity, reduced treatment costs, expansion of treatment population and reduced production costs might be employed. While reviewing candidate techniques, ECON will evaluate whether the economic techniques are applicable to the evaluation of disease treatment benefits related to the list of benefit classification categories of the candidates. The following examples are typical of candidate substances:

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\* Preliminary Benefit Analysis of Biological Space Processing, ECON, Inc., September 1, 1976, Contract NASW-2558, ECON, Report No. 76-119-1.

- Erythropoietin
- Lymphocyte Subgroup Fractions
- Human Growth Hormones
- Urokinase
- Human Insulin
- Vaccines.

Based on current knowledge, it is estimated that this list could be expanded to some 30 to 50 candidates during Phase I of this study.

The criteria to be utilized in choosing the appropriate evaluation technique are: (1) it is generally accepted by the health treatment community; (2) it is easily understandable and can be transferred to NASA for internal use if desired; (3) it offers the appropriate degree of accuracy and sophistication without being overly complex; and (4) the results are capable of being compared with each other and with the results of other studies.

ECON will then select one or more techniques to be utilized in this study.

2.1.2 In the second task of Phase I, ECON will analyze each of the the disease treatments corresponding to the candidates for space bioprocessing and determine precisely what data are needed and in what form the data should be before an evaluation of the economic benefits related to that disease treatment. Several man-days will be spent on each candidate product to determine what disease or diseases the new product would treat, what the present treatment modes are and what the potential new treatment techniques would be.

For the 30 to 50 candidate substances, ECON will determine the information needed for the economic evaluation of each candidate. NASA will supply ECON with sufficient information about each candidate biological substance or process to allow ECON to chart out what further data on costs, statistics incidence of disease, treatment state, transition probabilities and production costs are needed for benefit evaluation. This breakdown will direct the detailed data gathering efforts of Phase II, and this information will then be used to perform the economic evaluation. Although several techniques might be chosen to evaluate the potential beneficial outcome of the candidate substances, the important criterion is whether the outputs of the evaluation techniques can be compared to each other.

ECON will produce a written description telling the user of the evaluation technique how to generically determine what information, expert opinions, historical data and treatment costs are needed to proceed with an economic evaluation. This guide could be utilized when any new candidate substance is to be evaluated. If more than one evaluation technique is utilized, this guide, through its logical progression of steps, would indicate the inputs needed for the particular technique that would be utilized.

2.1.3. The final task of Phase I will be to prepare a detailed work plan for Phase II. The work plan will describe the data gathering, analysis and evaluation to be performed in Phase II.

## 2.2 Phase II--Data Collection and Benefit Evaluation

The thrust of Phase II will be to actually gather data needed to conduct and to perform the benefit evaluation once the necessary data have been collected. The evaluation techniques chosen in Phase I will be utilized in Phase II to produce an economic measure of the potential benefits possible from

pursuing space processing of each candidate pharmaceutical substance. It is anticipated that the results of the Phase II benefit evaluation could be used for a preliminary ranking of the candidate projects according to the size of the anticipated benefits. The evaluation of benefits in Phase II will be performed with the assumption that each project has a probability of success of 1.0. The estimated probability of success and failure will be considered in a decision tree analysis to be performed in Phase III. Phase II tasks are detailed below.

2.2.1. ECON will collect the data necessary to perform the benefit evaluation analysis.

2.2.2. Once the necessary data are collected, ECON will utilize the benefit evaluation techniques chosen in Phase I to produce numerical results. In ECON's previous work, the results were expressed under two forms of benefits: economic and social. The economic benefits will be expressed in terms of the magnitude of savings available over present health care costs, the improved earnings possible through improved health or the savings possible through a decrease in the cost of medication or vaccines. The social benefits relative to improved physical well-being might include potential years of extended life, number of years of improved health, reduced number of deaths or aversion of potential epidemics.

2.2.3. The final task of Phase II will be to prepare the detailed work plan for Phase III and to specify the computer program needed to perform the analysis of Phase III.

### 2.3 Phase III--Program Analysis and Evaluation

It is widely recognized that the possibility of complete success of both the space processing and subsequent earth-based utilization of the candidate

substance for medical treatment may be low in many cases. This low chance of success should be evaluated in relation to the often large potential economic benefits that could accrue from a successful outcome. To do this one must explicitly take into account the effect of uncertainty and risk.

In Phase III, ECON will arrange candidate substances or processes in a decision tree fashion, along with other factors of a bioprocessing program. Costs will then be assessed for each branch of the tree and probabilities of success and failure will be determined for each branch. The program options will then be evaluated to determine their probability of success. The values for the total benefits possible for each of the candidate substances, obtained in Phase II, will be utilized at this point to perform a rigorous economic comparison of alternative program plans.

It is anticipated that by the start of Phase III, NASA will have developed the methodology for cost apportionment for Spacelab missions and a cost-benefit analysis can be performed as a part of this phase.

### **3.0 Milestone Schedule**

**Figure 3.1 is the Milestone schedule for this Work Order.**

### **4.0 Manpower Planning**

**Figure 4.1 shows the manpower planning for this Work Order.**

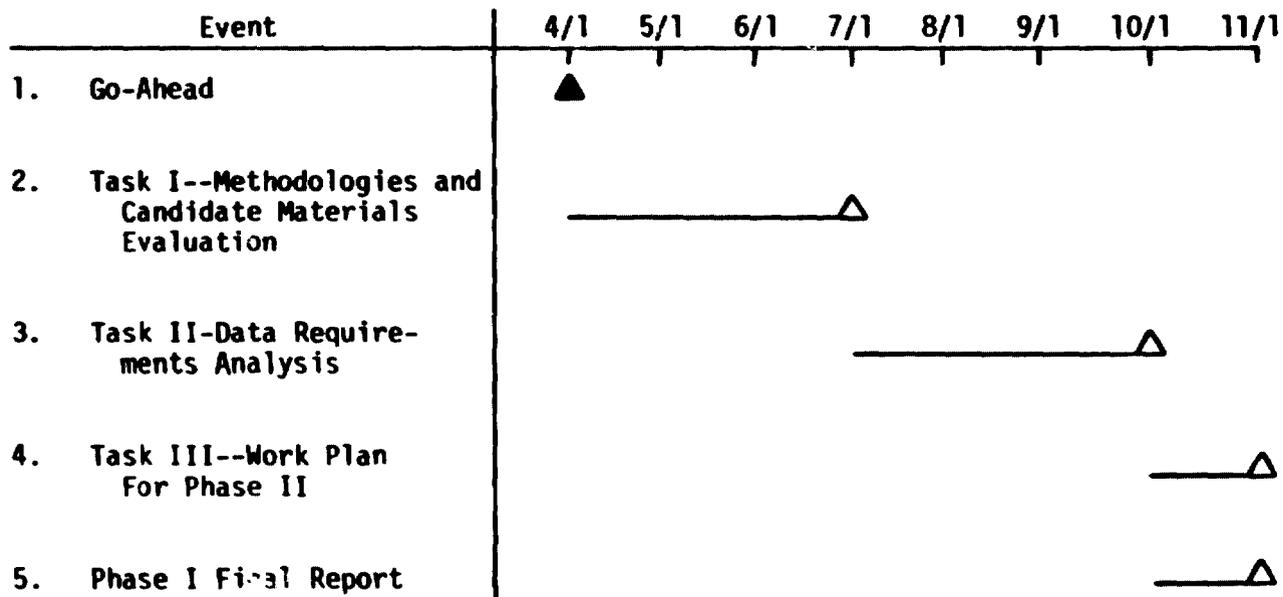


Figure 3.1 Milestone Schedule for Space Bioprocessing-Phase I

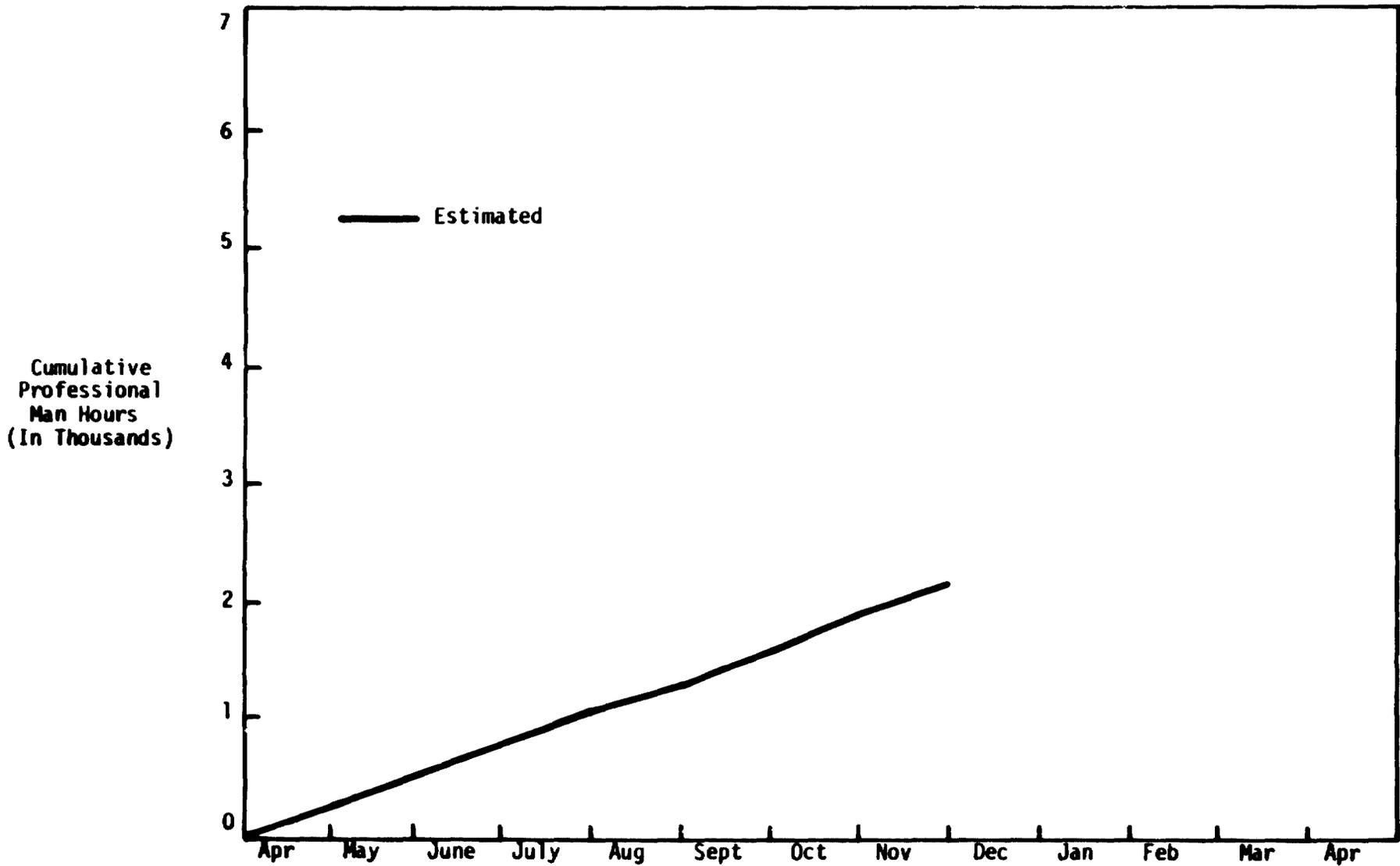


Figure 4.1 Manpower Planning Chart for Space Bioprocessing