ASSESSMENT OF THE LABORATORY ANIMAL DATA BANK
IN MEETING NEEDS OF USERS

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FOREWORD

The Life Sciences Research Office (LSRO), Federation of American Societies for Experimental Biology (FASEB), provides scientific assessments of topics in the biomedical sciences. Reports are based upon comprehensive literature reviews and the scientific opinions of knowledgeable individuals engaged in work in specific areas of biology and medicine.

This report is the second technical report prepared for the Specialized Information Services Division, National Library of Medicine (NLM) by Philip L. Altman, Senior Staff Scientist, LSRO, in accordance with provisions of Contract No. N01-LM-8-4736.

The LSRO acknowledges the contributions of the consultants who assisted with this study. The report reflects the opinions expressed by members of the LSRO ad hoc LADB User Assessment Panel II who are identified in Section VIII. A judicious attempt has been made to incorporate the various viewpoints and opinions of the knowledgeable scientists. The report was reviewed by these consultants; however, the listing of their names in Section VIII does not imply that they endorse all suggestions and recommendations of this study. The LSRO accepts responsibility for the contents of this report.

This report was reviewed and approved by the LSRO Advisory Committee (which consists of representatives of each constituent Society of FASEB) under authority delegated by the Executive Committee of the Federation Board. Upon completion of these review procedures, the report was approved and transmitted to NLM by the Executive Director, FASEB.

While this is a report of the Federation of American Societies for Experimental Biology, it does not necessarily reflect the opinion of each individual member of the FASEB constituent Societies.

December 31, 1980
Date

Kenneth D. Fisher, Ph.D.
Director
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SUMMARY

I. Introduction to the Study -- the Laboratory Animal Data Bank (LADB) is a computerized resource of comparative baseline data and reference information on various species and strains of animals commonly used in biomedical research. In April 1980, the National Library of Medicine (NLN), which monitors and administers the database, made LADB available to public users. In the fall of 1980, NLM requested that the Life Sciences Research Office of the Federation of American Societies for Experimental Biology form a panel to assess the performance and capabilities of LADB in meeting user needs. The User Assessment Panel II met on 20 and 21 November 1980 to discuss LADB and make recommendations as requested.

II. User Needs -- LADB provides a unique service unobtainable elsewhere; its ultimate utility will be unparalleled with the addition of sufficient data.

A. Adequacy of Data -- currently available data permits only limited comparisons and analyses. Concerted efforts should be initiated to collect additional data and such efforts should focus on the two most frequently used animal species: mice and rats.

B. Individual Animal Data File -- should be put on-line to accommodate user needs and to generate citable reference publications.

C. Data Quality -- currently adequate and expected to improve as Good Laboratory Practice (GLP) rules and regulations are universally applied. Evolving data acceptability criteria must be maintained, but NLM leadership and a peer review group will be necessary to monitor quality of data submitted for LADB entry.

D. Ease of Use -- LADB will be improved by making the individual animal data file accessible on-line, and by adopting a number of modified format procedures, such as summary tables preceding pathology printouts, code legends repeated on each page of the report, retrieval of environmental and management factors at the end of a search, and a memory for saving search statements.

III. Procedural Activities -- it was assumed during LADB development that the laboratory investigator would search the database; experience to date has shown that the information specialist is the prime searcher and the laboratory investigator the ultimate user. Current users suggested a number of specific procedural improvements.

A. Structured Search vs. Direct Search -- a shift in emphasis from structured search to direct search appears desirable and useful because of the presence of the information specialist between the database and the scientist.
B. User Training -- the training sessions received uniformly high marks, but an additional day should be devoted to the direct search mode.

C. Hotline Response -- the hotline has an excellent reputation, but a constant live-response system is considered essential if user needs for prompt responses are to be met.

D. Additional User Services -- an updated "User Manual" with notification of its useful life and expected dates for supplements is considered essential. A "Newsletter" and on-line news format to keep users current on new developments would be most helpful; publicity or promotional material is needed for distribution to potential users; and, regularly scheduled meetings with user groups to discuss necessary improvements would be desirable. In addition, an updated "Table of Contents" distributed at regular intervals, translations of code to natural language on-line, and a statistical package for pathology data are recommended.

IV. Data Acquisition -- collection of additional data for LADB must be the major goal of the project during the next several months. The LADB staff should develop a detailed plan of action which would include donor incentives, follow-up of initial contacts, and assistance in data input. Efforts should be focused on obtaining mouse and rat data, but all data offered should be accepted for review. Emphasis should be placed on obtaining data from various U.S. Government agencies and institutes.

A. Donor Incentives -- credit or exchange, free or discounted, on-line time for data submitted and accepted is an immediate potential incentive. For incentives long range, 1) a greater concentration on collecting rat and mouse data will enhance utility of LADB to users who are, in actuality, a major source of donors; and, 2) efforts to coordinate regulatory agency guidelines, data forms, and information surveys related to GLPs with LADB guidelines for data acceptance and data forms would benefit potential donors. Control animal data for GLPs is a potential source of data for LADB if the Food and Drug Administration would agree to have LADB serve as a repository for GLP historical control information, exclusive of privileged data.

B. Plan of Action -- appoint a contact-scientist well accepted among biologists; work with the potential data donor; develop a follow-up schedule to assure receipt of data; maintain contact for future additional data contributions.

C. Sources of Data -- agencies represented on the Toxicology Information Subcommittee of the Department of Health and Human Services (DHHS) Committee to Coordinate Environmental and Related Programs should assume a greater role in submitting data collected within or by their own agency units. LADB staff should seek out data from other Federal agencies.
V. **Funding** -- administrative responsibility for LADB is derived from the DHHS Committee to Coordinate Environmental and Related Programs, through its Toxicology Information Subcommittee. Since 1975, LADB has been funded by several Federal agencies and organizations, including NLM. This fiscal support has been focused on research and development; support for the next three years is required for acquisition of data.

A. **Government Sources** -- the National Library of Medicine has managed LADB since its inception and should continue to do so for a three-year period. The Library should maintain some fiscal commitment as a component of its managerial role. Support from various governmental units and other sources will be required over the next two years to provide for acquisition of data. Support should be sought by the LADB Task Group of the Toxicology Information Subcommittee from those agencies that can reap the greatest benefit from LADB, such as the National Institutes of Health, the National Toxicology Program, the Food and Drug Administration, the Environmental Protection Agency, the Department of Transportation, and other Federal organizations with programs involving animal studies.

B. **Private Sources** -- support should be sought from organizations with extensive investments in laboratory animal toxicology studies, such as the Chemical Industry Institute of Toxicology, the Chemical Manufacturers Association, the Pharmaceutical Manufacturers Association, and others.

VI. **Cost-Effectiveness** -- six months of public use was considered inadequate for any conclusions on cost-effectiveness, but developmental costs of LADB have been neither significantly greater nor lower than those of other interactive databases developed since 1972. Analysis of cost-effectiveness should be a component of the plan for LADB activities over the next three years.

VII. **Evaluation, Administration, and Staffing** -- LADB has suffered from diffuseness in these areas; plans of action with clearly identified performance goals must be developed and specific directions for meeting these goals implemented.

A. **Advisory Committees** -- evaluations should be reduced and a schedule developed for coordinated evaluation and review every two or three years.

B. **Staff Cooperation** -- a plan of LADB activities should be developed to cover the next three years; more specific direction for achievement of detailed goals must be developed and communicated by the LADB Project staff; a more dedicated commitment is required from Battelle Columbus Laboratories (BCL), including punctuality in delivery of promised items; NLM must conduct a vigorous public relations campaign to attract LADB users.
C. Accountability — contract language must be sufficiently precise to indicate exactly what the LADB staff expects; by this means, the BCL staff will be aware of what tasks and performance are required. Clearly identified statements of work are necessary to accurately measure contractor performance.

D. Administrative Transition — the plan for LADB activities should be developed by the LADB Task Group and LADB staff prior to April 1981. The plan should be based on transition of LADB from the public to the private sector over the next three years, but should include provision for control of data acceptance criteria by a designated Federal organization such as NLM, as well as a system for peer review of submitted data.
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I. INTRODUCTION TO THE STUDY

The Laboratory Animal Data Bank (LADB) is a computerized, on-line interactive data retrieval and manipulation system containing descriptive information and baseline biological data on selected strains of laboratory animals. Currently, the disciplinary coverage includes clinical chemistry, growth and development, hematology, and pathology. The LADB provides comparative data on characteristics of control animals of several species and strains. Using LADB, scientists may 1) select and examine baseline data for various biologic and physiologic values; 2) determine the environmental and management conditions for each animal group selected; 3) determine incidence of certain pathologic changes in animals; 4) statistically analyze the retrieved data; and 5) print out the data as distributions, such as data tables or histograms, and as complete reports.

LADB was made available to public users on a subscription basis in April 1980 by the National Library of Medicine (NLM), which monitors and administers the project (Appendix I). By mid-summer, the Toxicology Information Program Committee (TIPCOM), the advisory group that provides guidance to NLM's Specialized Information Services (SIS), concluded that the importance and utility of LADB to its user community should be determined prior to its continuation or expansion. By obtaining answers to a number of questions (see Appendix II, A-11), TIPCOM members concluded it would be possible to decide whether this data bank had broad utility, was an adjunct to animal research, or was merely a convenience to selected users.

In the fall of 1980, NLM responded to the TIPCOM proposal by requesting that the Life Sciences Research Office (LSRO) of the Federation of American Societies for Experimental Biology form a panel to assess the performance and capabilities of LADB in meeting the needs of scientific users. The Library indicated that in its review LSRO should include an assessment of the following areas which had been identified by TIPCOM:

1) Concepts and purposes of LADB;

2) Data quality procedures utilized in processing and entering data;

3) Procedural activities providing on-line and off-line search capabilities, user training, and other user services of LADB; and,

4) Assessment and recommendations for present and future needs including:

   a) Funding and funding sources.

   b) Cost-effectiveness of LADB.

   c) Program sponsorship, administration, and staffing.
Specific issues to be addressed, if possible, included the following:

1) Cost recovery based on user charges;

2) Identification of alternate sources of support for the project;

3) NLM as the proper organizational unit of the Federal government to manage LADB; and,

4) Adequacy of personnel resources for the task should NLM continue to manage LADB.

Accordingly, this report is limited to an evaluation — of user needs; procedural activities; data acquisition; funding; cost-effectiveness; and evaluation, administration, and staffing — by an ad hoc group of public users. Other aspects of LADB development and operation have been and are being reviewed by a number of other groups. For example, the Institute of Laboratory Animal Resources (ILAR) Executive Committee of the National Academy of Sciences/National Research Council (NAS/NRC) is responsible for the general overall evaluation of LADB, including its basic concept, purpose, scope, validity, and application (see Appendix II, pp. A-7 to A-9). In addition, as noted above, the NAS/NRC TTPCOM assesses LADB's role within the Specialized Information Services of NLM. LADB progress and direction, in terms of Federal government agencies needs and views, are monitored by a review panel (the LADB Task Group) of the Toxicology Information Subcommittee (TIS) of the Department of Health and Human Services (DHHS) Committee to Coordinate Environmental and Related Programs (CCERP). The LSRO ad hoc LADB User Assessment Panel I is responsible for evaluation of existing policies and guidelines for data acceptability, and the LSRO Data Acceptability Review Group is assessing submitted data in terms of the revised guidelines for data quality (see Appendix II, pp. A-9 & A-10).

The new group formed by LSRO to assess user needs was designated "LSRO ad hoc LADB User Assessment Panel II". The names and organizational affiliations of the Panel II members are listed in Section VIII, Study Participants. This Panel met on 20 and 21 November 1980 at Federation headquarters in Bethesda, Maryland. As a prelude to the meeting, a review of the LADB was provided by NLM staff, and an analysis of the reports of various advisory groups, as well as other information, was conveyed by LSRO staff (see Appendix II). The background document, Appendix II, had been sent to User Assessment Panel II members prior to the meeting in order to acquaint them with the comments and recommendations of the several advisory bodies referred to in previous paragraphs.

Based on the problems identified in the background document, and in the briefing by NLM and LSRO staffs, the Panel conjectured that several courses of action were open to NLM concerning the future maintenance of LADB. These options included the following:

1) Federal sponsorship of LADB should be discontinued in the near future and the database sold to a commercial vendor on the open market.
2) Funding should be maintained at its current level, but a plan should be developed for phasing out Federal sponsorship and support over the next 12 months.

3) Funding should be maintained for a three-year period while a plan is developed for strengthening the database by accelerated data acquisition, and turning over LADB operation to a private vendor but having NLM retain control of data acceptance criteria.

4) Sponsorship should be shifted to some other Federal agency that would be responsible for funding LADB, but NLM would retain data acceptability control for a limited agreed-upon period.

5) Sponsorship should be shifted to another Federal agency that would accept the administration and management of LADB as a total programmatic unit.

This report is a synopsis of the ensuing deliberations and recommendations of Panel II with respect to LADB, as a publicly available database (April to November 1980), in meeting the needs of its scientific users.
II. USER NEEDS

In discussing options for the future of the Laboratory Animal Data Bank (LADB), the Panel concluded that LADB provides a unique service as an on-line repository for historical control animal data, a means for data comparison from different sources, and a source of scientific data manipulable by the user. No other published, unpublished, or on-line resource provides a similar service or set of services.

As a resource for historical control data that can be used for comparative purposes, LADB will be unparalleled once the number of observations reaches a sufficient quantity. However, this does not intimate that LADB will replace an investigator's need to include experimental control animals, although the potential for reducing the number required should not be overlooked. To a somewhat lesser degree, LADB can be used for selecting animal models if more data are made available for the strains included in the database, and for improving experimental design by determining the effects of environmental and management factors on various parameters. The statistical package is a useful adjunct to LADB because it permits user initiated statistical analysis of data. Further refinement of the statistical program would provide a means for using additional analytical procedures.

Recommendation: The first five years of LADB can be considered a developmental phase. Though experience is limited, the recognition of LADB's potential suggests it should be continued, but with some reorientation of goals.

A. ADEQUACY OF DATA

Despite the generally recognized potential of LADB, it is marginally useful at present because the quantity of data in the bank is insufficient to meet the needs of all users. Subject coverage for the animals in LADB is inadequate, despite the approximately one million observations in LADB (Appendix III). These data represent only a fraction of the observations necessary, for as the user narrows a search based on selected factors, the retrieved group data frequently contain too few animals to provide meaningful information or statistical comparisons. In addition, the bulk of the data in LADB comes from a single source—the National Toxicology Program/National Cancer Institute (NTP/NCI) Carcinogenesis Bioassay Program—thus compromising the theoretical possibility of comparing rodent data from multiple sources. The usefulness of the NTP/NCI data will be markedly enhanced when data from other sources are available for comparison.

Recommendation: After discussing the range of species included in LADB, members of the Panel endorsed the conclusion contained in the 1979 ILAR Report which strongly suggests that rodents are the primary species of interest (see Appendix II, p. A-8). Therefore, the focus of the next three years should be on a concerted effort to collect mouse and rat data. The objective should be to add, materially, data from sources other than the NTP/NCI Carcinogenesis
Bioassay Program to the rodent database already available, while continuing to accept new data from that source as well. It is essential that subject coverage be supplemented so that the mouse and rat files are expanded with respect to all data elements.

While primary emphasis in solicitation and collection should be placed on rodent data, expansion of all animal files is also desirable and necessary. If data on other animals, especially primates, are submitted voluntarily, they should be accepted for review. However, the more complete the LADB files on mouse and rat data, the greater their utility to users. This, in turn, will generate more user and donor interest and, subsequently, will produce more data submissions on all animal species.

B. INDIVIDUAL ANIMAL DATA FILE

The LADB user is unable to control how animal groups are established and what criteria determine group size because the individual animal data file (IADF) is maintained off-line. The ability to access this file on-line can provide a method for batching or grouping animals according to the needs of the user. Should the file of rodent data grow as expected, the distinction among groups will become less meaningful except to users who will, by asking specific questions, create groups from the data pool. Thus, preformed groups will be a deterrent to user goals.

Recommendation: The full potential of LADB will be realized when the IADF is put on-line. The LADB users must be able to develop search strategies composed of factors of their own choosing. By putting IADF on-line, other benefits can result as well, such as the generation of marketable data books or monographs for those who are unable to obtain direct on-line services. In turn, this assures the availability of a literature-citable source, and a new source of income from the sale of LADB-produced publications.

C. DATA QUALITY

While the User Assessment Panel II had agreed originally not to include the subject of data quality in its deliberations, this proved to be impossible. Members of the Panel noted that one of the chief concerns of the LSRO ad hoc LADB User Assessment Panel I was the improvement of the quality of the data being entered in LADB. The Panel II members concurred with the tightening of quality assurance procedures as specified by Panel I in the new "Guidelines for Data Acceptance Criteria". For example, the old guidelines permitted inclusion of data from negative, sham, and vehicle controls, as well as quarantine and pre-test animals. The new criteria specify that data must be from animals not experimentally manipulated other than to establish normal physiological baseline values by accepted methods. Approved animals must be healthy negative controls and those from breeding colonies. Data from minimally manipulated vehicle and sham control animals will be considered for acceptance only if such data are not available from approved animals. Data from animals in quarantine or before they go on test (pre-experiment) will not be accepted.
Another improvement in quality assurance with which the Panel members concurred is the recommendation that data elements be categorized on a priority basis as a major criterion for data acceptance. This revised criterion establishes 13 data elements covering the performing laboratory, data donor organization, testing organization, animal supplier or breeder, as well as animal information -- species, strain, sex, age, mating parentage, microbial status, and type of control -- as essential for all subject areas. Unless all of this information is submitted for each animal group, the data will not be accepted. In addition to the 13 essential data elements that must always be provided, certain information on environment and management is considered mandatory for each subject area covered in LADB; for Growth and Development, 28 additional elements will be required, for Hematology 41, for Clinical Chemistry 37, and for Pathology 31. They cover lighting, temperature, humidity, animal enclosures and disinfectants, bedding, feed, water, and vaccinations, as well as date of birth or animal age in months, and month and year of observation.

The Panel also concluded that one of the most important steps in data quality control will be the establishment of a permanent Data Acceptability Review Group (DARG) of scientific experts to determine if data submitted for LADB should be unconditionally accepted, provisionally accepted, or rejected in accordance with the newly formulated "Guidelines for Data Acceptance Criteria." At the present time the LSRO ad hoc DARG, a forerunner of the anticipated permanent group which would report directly to the LADB Project Officer, is reviewing submitted data packets utilizing the new criteria. The User Assessment Panel II was aware that this review is not yet complete.

Based on these developments, the members of Panel II concluded that the quality of data being entered into LADB will continue to improve as these revised procedures are adopted. The Panel members commented that LADB users must rely on the built-in measures of data quality assurance because the users are at a disadvantage in judging quality when they view only the output and not the input. Panel II agreed that acceptance of validity of data in the bank would be enhanced when there is general recognition that peer review of submitted data is a necessary criterion for LADB input.

The Panel noted additionally that an opportunity to further improve the quality of LADB data will be afforded by the FDA's implementation of the Good Laboratory Practice (GLP) rules and regulations for care and handling of laboratory animals [21 CFR 58].

It should be noted that as many of the data acceptance criteria have been developed and implemented, the quality of the data entered in LADB has continued to improve. The implementation of the Good Laboratory Practice (GLP) rules and regulations for care and handling of laboratory animals [21 CFR 58] by the FDA affords an opportunity to further improve the quality of LADB data. It should be noted that many of the data required of experimenters for compliance with the GLPs are similar to data requested by LADB of potential donors. Because most donors will ultimately be required to meet GLPs, it would be efficient to ask investigators to provide data only once. In addition, LADB could, with FDA agreement, serve as a repository of historical control data. Organizations and individuals could reference LADB in meeting GLP requirements rather
than continually submitting data on animal facilities. Should such a cooperative venture prove feasible and efficient, it is critically important that LADB be a repository and maintain its own data acceptance criteria. Similarly, FDA has an obligation to maintain its regulatory functions, including review and maintenance of files containing privileged information not available to LADB. These two parameters would need to be made clear to all parties.

**Recommendation:** The recommendations of the LSRO ad hoc LADB User Assessment Panel I and the Data Acceptability Review Group were endorsed by the Panel. Users of LADB must be made aware that the information in the database is not all of the same quality because it comes from different sources. Perhaps, in time, this will be unnecessary as quality control reaches accepted standards of excellence. For now, NLM leadership is required to maintain the improved data acceptability criteria, and to establish a permanent Data Acceptability Review Group charged with 1) evaluating questionable data, and 2) assessing the desirability of data that do not meet all of the acceptability criteria but might nevertheless merit inclusion in LADB.

The LADB Task Group, as a unit of the Toxicology Information Subcommittee of the DHHS Coordinating Committee, and the LADB staff should initiate discussions with FDA staff who are responsible for implementation and monitoring of the GLP regulations on care and handling of laboratory animals. The criteria for acceptability of data to be included in LADB are of potentially great value to the scientific community because of their similarity to FDA's guidelines covering GLP requirements. It would be useful to consider only one data form required for both GLP and LADB data input. Such a step would add quality control and improve efficiency as well as reduce investigator anxiety with respect to data record keeping.

**D. EASE OF USE**

At the present time, individual animal relationships cannot be determined because the IADF is not on-line. For example, the correlation of a clinical chemistry file variable with a pathology file variable is not possible.

Current usage patterns suggest pathology data are accessed more than any of the other data in LADB. However, the retrieved data are often so voluminous that they compromise ease of use.

**Recommendation:** In order to achieve cross-file correlations of two variables and to automatically evince their interrelationships, the IADF must be accessible on-line.

When requesting a pathology printout, in order to avoid lengthy detailed reports if only summary values are required, it is recommended that the user be afforded the option of requesting that the report be printed with either the detailed values broken down by age group, or a summary of the total values.
Another recommendation, specifically related to pathology data, was repetition of the legend for codes that appear on the first page of the pathology printout; that is, code legends should appear at the top of each page of the printout.

Similarly, software reformatting of the environmental and management factors should permit their retrieval at the end of a search. It would be useful, too, if the system had a "STORE SEARCH" memory for saving search statements similar to that of NLM's bibliographic databases.
III. PROCEDURAL ACTIVITIES

Since inception and throughout development, the user of LADB has been assumed to be the laboratory investigator. Experience since April 1980 indicates that the scientist is the ultimate user, but the individual conducting the data search is more likely to be an information specialist or a laboratory worker familiar with computerized storage and retrieval of data. However, greatest efficiency is achieved when the scientist and information specialist search the database together. As confidence between the two is developed, the scientist can defer to the information specialist in the conduct of routine searches. As younger scientists, whose training includes computer search techniques, become established investigators, it is possible that LADB will be used directly as was originally intended.

A. STRUCTURED SEARCH VS. DIRECT SEARCH

The practical on-line search capabilities of LADB were constructed for the non-expert user unfamiliar with interactive database utilization and for the occasional user. However, even these users find the constant repetition of choices in the structured search mode a tedious and time-consuming exercise. A refinement of the structured search can be easily achieved because the BASIS software used by BCL is quite flexible and convenient to modify. The customized (erroneously referred to as off-line) searches offered by BCL afford a useful alternative to difficult or lengthy on-line searches.

Recommendation: The presence of an information specialist between the database and the laboratory scientist necessitates a shift in emphasis from the structured to the direct search mode. The proficiency of the information specialist in computer searching demands that the direct mode become the primary search technique with the structured mode relegated to a secondary, backup position. This does not imply that the structured search be abandoned; it only suggests that some experienced information specialists find it cumbersome, repetitious, and slow. A structured search profile can be built that will reduce steps and time in retrieving data for the occasional user who requires prompts. For the frequent user, even such a modification will not serve the purpose; a more broadly formatted direct search can be used to advantage by the information specialist, as well as the scientist-user experienced in computer searching.

B. USER TRAINING

Based on experience gleaned since May 1980, the BCL instructors involved in LADB user training sessions are highly esteemed for their competence in teaching an entirely new, non-bibliographic computer system. However, training would be further enhanced by use of a "User Manual" with a pre-announced lifetime and a pre-announced schedule for "User Manual" supplements.
Recommendation: To achieve the shift, indicated above, from the structured to the direct search mode, it is recommended that the training sessions be extended to three days with the third day devoted to a thorough explanation of, and hands-on experience with, the direct search mode. Additionally, the "User Manual" should contain as complete a description, with examples, of direct searching as is presently devoted to structured searching (see also Item D, Additional User Services). The training session should also provide information on how the off-line search differs from on-line searching, and what are its capabilities so the user can decide when its use would be preferable.

C. HOTLINE RESPONSES

The responses of BCL personnel to "Hotline" requests for assistance are considered to be highly satisfactory. Every effort is made to provide relevant answers to questions, as fully and courteously as possible.

Recommendation: The excellent reputation of the "Hotline" is marred by the frustrations engendered when the user must leave a transcribed message for subsequent callback. A constant live-response system should be made a standard part of BCL user services.

When a problem cannot be solved quickly, the user should be given an approximate date on which a response can be expected. After a list of known problems requiring lengthy solution times are known to BCL, they should be conveyed in the "Newsletter" (see Item D.3 below) frequently and accurately to aid the LADB user.

D. ADDITIONAL USER SERVICES

The "Hotline" and the customized searches are services that do provide the user with answers to questions and do retrieve the data if they are in LADB. However, a number of other user services are of equal or, perhaps, greater importance.

Recommendation: The following services designed to meet the user's needs should be implemented as soon as possible:

1) A revised "User Manual" that contains historical background material on LADB, complete definitions of terms, and a comprehensive presentation of the direct search mode should be provided. (Advantage should be taken of MEDLINE and other NLM databases' experiences in user manual preparation.) The manual should be distributed to all users and employed for a pre-announced lifetime.

2) Stabilization of the system and of the "User Manual", with the achievement of consistency between the two is essential. Timely supplements, containing necessary explanatory information, should be distributed once or twice a year.
3) A "Newsletter" should be sent to subscribers and included on-line to keep users current on new developments and on reasons why certain changes are being made. The "Newsletter" should be distributed monthly and the on-line news format should be updated as often as necessary.

4) Publicity or promotional material for distribution to potential users is needed by all organizations and individuals with user agreements. This material should describe what is contained in LADB and how it can benefit the user. Information specialists have a pressing need for such material to inform scientists about LADB.

5) Greater opportunity for user feedback should be provided by regularly scheduling meetings with user groups to discuss deficiencies and necessary improvements.

6) The "Table of Contents" should be updated and distributed at regular intervals; additions to LADB should appear also as "news items" on-line.

7) Table-driven translation of code to natural language on-line is needed to facilitate or enhance immediate explanations of codes in printouts of results.

8) Statistical analysis of pathology data is not possible at present because they are not entirely quantitative. However, a statistical package should be added for the quantitative pathology data in LADB as they become available on-line.
IV. DATA ACQUISITION

The acquisition of additional data for LADB must be the major goal of both NLM and BCL. Unless there is sufficient data in the system to meet the needs of users, LADB will stagnate. A large number of prospective data sources have been identified in the past several years, but now it is essential that a coordinated effort be mounted to complete the collection process successfully (Appendixes IV, V). As noted previously, LADB staff efforts should be focused on obtaining rodent data. A major thrust in the months ahead should be acquisition of mouse and rat data to build these files substantially (see also Section II, Item A).

A. DONOR INCENTIVES

The difficulties in acquiring data are well recognized and should not be underestimated. They are attributable to 1) low priority and lack of incentive on the part of potential donors to collect and submit data, 2) fear of exposing deficiencies in laboratory animal control data that might reflect unfavorably on the contributing organization or individual, and 3) lack of persistence in pursuit of data. Although some prospective data donors consider LADB a logical repository for their control data, they have doubts about being able to retrieve data in a form that meets their requirements.

Recommendations: The potential donors must be given incentives for contributing data to LADB. By providing a vehicle or mechanism whereby contributing organizations can use LADB and its software capability as their own repository for control animal data, a change in attitude may be effected. One readily adoptable incentive to consider is the provision of a given amount of free on-line time in exchange for data accepted for inclusion in LADB.

Individuals and organizations conducting experiments using laboratory animals could have a vested interest in getting their data into LADB because it could easily fulfill the Good Laboratory Practice (GLP) rules and regulations [21 CFR 58] for a historical control database. If LADB were recognized as a repository for data (other than privileged information) required by the GLP guidelines, collection and submission of such control animal data would be a desirable and efficient method of record keeping. Such an arrangement will require the cooperation of the Food and Drug Administration in accepting LADB as an official data repository for organizations complying with the GLPs. In addition, it will mean the establishment of procedures, protocols, and formats that are compatible with GLP requirements. For example, if the LADB input form ("Animal Group Environment and Management Conditions" Questionnaire) is consistent with the proposed GLP input form, the donor can submit a single form that satisfies the quality control requirements of both. Representatives of the TIS and NLM/LADB staff should initiate discussions with responsible FDA personnel and engage in a meaningful dialogue on implementation of mutually useful interactions.
Many organizations have raw data stored on magnetic tape. LADB should access magnetic media formats exclusively rather than having to keypunch raw data. Many organizations may be willing to permit use of these computerized internal files. This mechanism provides for quick accession, and allows the donor to retain control of what data are made available. It has the added effect of shortening the time between data acquisition and its appearance online.

B. PLAN OF ACTION

Some of the problems related to data acquisition can be resolved by developing a plan of action in which the efforts of NLM and BCL are closely coordinated. The specifics of such a plan can be worked out between the NLM/LADB staff and the BCL/LADB staff, but the general principles were outlined in the Panel discussions. The development of a plan of action is considered an essential component of responsible management.

Recommendation: The NLM/LADB Project staff should develop a phased plan of action for the next three-year period by April 1981. The plan should have clearly identified performance goals and specific directions for meeting these goals. The plan should have some input from BCL staff and the LADB Task Group; it should, when fully agreed upon, receive the imprimatur of the TIS and be incorporated into the work statement of the contractors.

The general plan for this growth phase for LADB should contain detailed guidelines and procedures for acquisition of rodent data, including the following:

1) The key individual in the acquisition process is the contact-scientist whose standing in the biological community must be such that this person can gain entry to the upper echelon of various organizations—pharmaceutical, chemical, and government laboratories, breeders and suppliers, university laboratories, as well as non-profit and private organizations with interests in experimental animal studies and toxicology testing. Scientist-administrators and prospective scientist-donors should be able to identify with the contact-scientist and have confidence in his or her scientific capabilities. Personal rapport between the individual making the contact and the individuals being contacted is most important, and often means the difference between a contribution of data and a tentative, unfilled promise. The contact-scientist should be a full-time, permanent member of the NLM/LADB staff.

2) Once the contact is made and the commitment to contribute data obtained, the contact-scientist must arrange to meet within a few days with the potential donor and a BCL information specialist assigned full time to data acquisition. After effecting a good working relationship between the latter two, the contact-scientist would move on to the next organization.
3) The information specialist would provide the necessary assistance in assuring proper formatting of the data, in filling out the LADB Questionnaire, and in making certain that the material can be processed when it is received by BCL.

4) A follow-up schedule should be prepared by the NLM and BCL staff members who constitute the two-person team. Persistence in pursuing initial contacts with subsequent personal visits and frequent telephone calls on a regular basis is crucial to success in acquiring the desired data. If data are not received at the time promised, prompt action must be taken in contacting the delinquent contributor, first by telephone and then in person.

5) It will be important to maintain contact with the donor even after the submitted data are accepted, processed, and entered in LADB. If the proper rapport has been established, data submissions can become an accepted practice as the scientist-donor generates new data. Regular contributions of data, rather than one-time submissions, should become the rule for LADB.

6) Once submitted, staff of the contractor should be responsible for scheduling data input into LADB as expeditiously as possible. This will require strict compliance with data acceptance criteria and review by the NLM/LADB Project Officer, and peer review as necessary. A schedule for such activities should be set up and followed.

C. SOURCES OF DATA

The procedures listed above are especially applicable as regards U.S. Government agencies, and the National Institutes of Health (NIH) in particular. Whereas considerable data have been obtained from the NTP/NCI Carcinogenesis Bioassay Program, little have been submitted by other Institutes.

Recommendation: Contacts must be established, good relations developed, and data collected from government agencies and institutes that not only generate data but require it as a result of their legislatively mandated responsibilities. These organizations, particularly those represented on the DHHS Committee to Coordinate Environmental and Related Programs as well as those generating data on federally funded intramural and extramural research projects, should be considered as donors because they are LADB beneficiaries (see Section V, Item A).
V. FUNDING

The administrative responsibility for LADB is derived from the Department of Health and Human Services (DHHS) Committee to Coordinate Environmental and Related Programs, through its Toxicology Information Subcommittee (TIS). However, funding for LADB over the past six years (1975-1980) has been supplied by several Federal agencies and organizations including NLM, and has exceeded $3,750,000, or approximately $650,000 per year (see Appendix II, Table 3). Whereas most of the expenses were required for the research and development of the system, a similar amount may be needed for an all-out effort over the next three years devoted to the acquisition of data.

A. GOVERNMENT SOURCES

Since its inception, the LADB's principal financial supporter has been the National Cancer Institute (NCI). This is related to NCI interest in having data generated by the Carcinogenesis Bioassay Program included in LADB. The recent transfer of this NCI research program to the National Toxicology Program (NTP) has led the NCI to indicate that it may reduce funding for LADB in fiscal year 1981. During the past six years, the other 42% of LADB's support came from the Office of the Assistant Secretary for Health (OASH), the National Center for Toxicological Research (NCTR) of FDA, the Interagency Regulatory Liaison Group (IRLG), the Office of the Director of NIH, and from NLM itself (see Appendix II, Table 3).

Other agencies and institutes of the Federal government engaged in research or requiring control data derived from animal experimentation should be involved in the partial support of LADB. No other database provides baseline biological data to its users. Not only should these Government facilities assume a dominant role in the support of LADB financially, they should be among its most prolific contributors of data. In both instances, the Government installations benefit; on the one hand, from providing the monetary resources that make possible the acquisition of data, and on the other hand, from contributing to and retrieving from a central repository of historical baseline control data.

Recommendation: Given the current and future financial requirements of LADB, the following plan for implementing support of LADB should be considered by the TIS of the DHHS Committee to Coordinate Environmental and Related Programs. These suggestions are based on the premise that the ultimate authority and administrative responsibility for LADB is derived from the DHHS Committee, through the TIS and its LADB Task Group.

1) The National Library of Medicine has been charged with management of the LADB since its inception and should continue to maintain the lead role in overall project management. It should maintain some fiscal commitment to LADB for three more years as a component of NLM's managerial role. Since the Toxicology Information Program initiated LADB within the Specialized Information Services
Division, the Library should support the data bank for the period necessary for LADB to achieve its potential as a viable, useful, and unique information resource.

2) The several components of the National Institutes of Health should support the development of LADB because they are recognized leaders in funding of experimental animal research and because both the intramural and extramural research programs of several institutes generate considerable data on a wide range of laboratory and other experimental animals. The TIS/LADB Task Group should approach the several institutes through the NIH Bureaus, Institutes, and Division Directors' Committee or the NIH Research Coordinating Committee. Efforts should be directed toward obtaining both interim funding and data for entry into LADB as well as providing access to LADB by NIH laboratories.

3) Funding should be sought from the National Toxicology Program/ National Institute for Environmental Health Sciences (NTP/NIEHS) to replace in part the support provided previously by NTP/NCL. Because NCI had supported the development of LADB as an adjunct to the Carcinogenesis Bioassay Program, and because NTP/NIEHS has absorbed this program, it seems appropriate that NTP/NIEHS as contributing members of the TIS, should help support LADB.

4) The FDA is a potential contributor because it is the lead agency in developing Good Laboratory Practice (GLPs) for nonclinical laboratory studies. FDA has developed and continues to improve guidelines, rules, and regulations with respect to standards for care and handling of laboratory animals [21 CFR 58] (see also 43 FR 59986-60025). The LADB could serve as a repository for historical control data (other than privileged information) collected in response to meeting GLP's. In addition, data collection records developed for LADB are potentially useful to FDA as a model for data records in support of GLPs.

5) The FDA and Environmental Protection Agency (EPA), as components of the NTP, are supporting animal experimentation at the National Center for Toxicological Research (NCTR). This Center is developing a toxicology data management system (TDMS) for acquisition, processing, and storage of experimental data. When operational, TDMS could be a direct source of data for LADB, and LADB a source of historical control data for on-line assessment of TDMS-generated data. Thus, FDA and EPA have additional reason to support LADB.

6) It should be noted that the Bureau of Veterinary Medicine, FDA, should be interested in LADB as a future source of data on larger experimental farm animals, such as cattle, horses, swine, and poultry. As the database grows, a name change may be indicated for LADB, thus indicating a wide range of experimental animals other than laboratory test species. (Such a plan or change should be considered in the future, and not before completion of the next three-year phase.)
7) Financial support should be requested from the EPA. LADB could serve as an adjunct database for the larger toxicology data testing and analysis system being developed for the Office of Toxic Substances. The laboratory animal control data would be valuable to the scientists reviewing test data submitted in compliance with Sections 4, 5, and 6 of the Toxic Substances Control Act (TSCA).

8) The Department of Transportation (DOT) mandates toxicity testing for certain chemicals transported in interstate commerce. Since LADB can provide baseline data supportive of such efforts, DOT should be solicited for funding.

9) The Department of Energy (DOE) is responsible for synthetic and alternate fuels programs that utilize toxicity data. An effort should be made to obtain some funding from DOE.

10) Other government facilities with programs involving animal studies should be approached by the TIS for funds, including those that have provided support for LADB in the past. However, all of the government agencies and institutes whose financial support is being sought should be informed that this request is for a finite period based on a time schedule of three years for the phasing out of public funding and the phasing in of private support.

B. PRIVATE SOURCES

Financial support from private organizations was not considered in the past because the research and development phase of LADB operation was government initiated and funded. Because emphasis on data acquisition will benefit the private as well as the public sector, efforts should be instituted to attract private sources of support.

Recommendation: Possible contacts in the private sector for support of LADB include the Society of Toxicology, the Laboratory Animal Clinical Analysis Group of the American Association for Clinical Chemistry, the Chemical Industry Institute of Toxicology, the Chemical Manufacturers Association, and the Pharmaceutical Manufacturers Association. These organizations may not provide direct financial support, but they could persuade member firms or individuals to contribute data. Trade associations should recognize the future need to contribute fiscal support in addition to data. All laboratories conducting toxicology testing should be candidates for data submission to LADB, and should be made aware of the proposed plan to have LADB phase into a joint venture ultimately funded primarily by user fees and other non-public funds.
VI. COST-EFFECTIVENESS

The connect hour cost to the user of on-line access to LADB is currently $20, with a $20 per month minimum charge. Users can also avail themselves of an off-line service through which customized searches are performed by BCL staff at a charge of $50-$250 depending on the personnel resources required for the response. Whereas the $20 per hour user charge supposedly pays for actual computer use and telecommunications costs associated with searching, it does not pay for file storage and maintenance of the database itself. The Panel was asked to evaluate costs and determine the charges realistically necessary to make LADB a cost-effective system.

The Panel agreed that the data provided on costs during the development of LADB and only six months of experience as a publicly available on-line system were inadequate for any conclusions on cost-effectiveness. However, there were comments from individual Panel members that ultimately a higher hourly and monthly charge (double or triple the present charge) or even an annual basic fee plus connect time charges would not be unreasonable if the database was sufficiently expanded and if the data could be retrieved more efficiently by the user.

The Panel concluded that from the data provided on developmental costs of other on-line information sources and data banks, it seems apparent that LADB costs are neither significantly greater nor lower than experienced with other databases developed since 1972 (Appendixes VI, VII). Analysis of total connect time for several NLM databases during their formative stages suggests a pattern of initial use that is analogous to total connect time experience for LADB during the first six months of public use (Appendix VIII). Future projections for LADB compare favorably with other databases, such as MEDLINE and HEALTH (Appendix IX), TOXLINE and CHEMLINE (Appendix X), and especially RTECS and TDB (Appendix XI).

**Recommendation:** An analysis of cost-effectiveness of LADB should be a component of the plan for LADB activities over the next three years. The figures required for an accurate analysis should be available within such a time frame.
LADB is sponsored by the DHHS Committee to Coordinate Environmental and Related Programs, an interagency group which is the successor to the original sponsor, the DHEW Committee to Coordinate Toxicology and Related Programs. The Toxicology Information Subcommittee (TIS) of the DHHS Committee through its LADB Task Group provides review, advice, and input with respect to the overall direction of LADB in terms of agency needs and views.

The LADB is administered by the NLM through its Division of Specialized Information Services (SIS). The NLM/LADB staff is located in the Lister Hill National Center for Biomedical Communications on the NIH Campus.

The LADB project staff also receives input from the following groups which review portions of the program:

1) The Committee on Laboratory Animal Data of the Institute for Laboratory Animal Research (ILAR), National Academy of Sciences/National Research Council. Since the inception of the database, this group has provided guidance on various aspects of LADB development, and conducted general evaluations of LADB periodically. The major recommendations proposed in the first evaluation report were assessment of quality control, scientific credibility, quantity of data, animal species and strains, animal groups, and data element descriptors (see Appendix II, p. A-7). The User Assessment Panel I and the Data Acceptability Review Group of the Life Sciences Research Office, FASEB, were formed by NLM in response to these recommendations. A second evaluation by the ILAR group a year (1979) later emphasized strong central management of LADB if the project is to succeed (see similar recommendation on p. 23).

2) The Toxicology Information Program Committee (TIPCOM) of the Board on Toxicology and Environmental Health Hazards of the National Academy of Sciences/National Research Council. This group provides guidance to NLM's Specialized Information Services (SIS); LADB, as an activity of SIS, falls under the purview of TIPCOM. Formation of the LSRO ad hoc LADB User Assessment Panel II to assess the performance and capabilities of LADB in meeting the needs of scientific users was based on recommendations of TIPCOM.

3) The ad hoc LADB User Assessment Panel I and the Data Acceptability Review Group (DARG) of the Life Sciences Research Office, Federation of American Societies for Experimental Biology. The Panel evaluated the criteria for acceptability of data submitted for LADB and developed new "Guidelines" designed to improve quality control (see Appendix II, p. A-9). The DARG is currently engaged in reviewing submitted data in terms of the revised "Guidelines", and on the basis of objective analysis rendering a scientific opinion on data acceptance or rejection (see Appendix II, p. A-10). This User Assessment Panel II is responding to TIPCOM's recommendation that the utility of LADB be determined in terms of its meeting user needs.
4) A number of special consultants engaged by SIS or the LADB staff. One such group is the Consultants on Animal Nomenclature. Highly qualified experts are asked to supply answers to specific problems and provide advice as needed. A group of experts may meet to decide on terminology to be used for specific animal characteristics in an effort to improve data quality assurance. Such individuals or groups deal only with one specific issue and once resolved, their services are terminated.

The LADB project staff consists of one veterinary scientist who is full-time Project Officer, one full-time temporary visiting veterinary scientist responsible for pathology nomenclature, one veterinarian who monitors LADB on a 75% basis, one full-time computer specialist, and a part-time (75%) secretary.

Battelle Columbus Laboratories is the prime software contractor with major facilities and staff in Columbus, Ohio, and a LADB project team in Vienna, Virginia. The entire BCL staff working on LADB fluctuates between 14-39 professional and 11-19 clerical personnel, with the former devoting about 1240 hours and the latter approximately 590 hours per month, or eight- and four-person years, respectively. Of the BCL employees, there are three information specialists, one of whom serves as LADB Project Manager with the other two responsible for data handling, data processing, and user support, as well as a biostatistician who is the Assistant Project Manager; they devote approximately 75% of their time to LADB. The scientific staff of BCL, which gives about 25% of its time to LADB, consists of a veterinarian who, as Associate Project Manager, is responsible for data solicitation, and three veterinary pathologists, who perform quality control and review of data, systems evaluation, project monitoring, module structuring, and respond to users' scientific problems.

A. ADVISORY COMMITTEES

The NLM/LADB staff makes presentations to and receives advice, counsel, and evaluation from a multiplicity of legally constituted and contractually engaged advisory groups. The nuances and complexity of the processes involved are difficult to comprehend and require considerable time on the part of the LADB Project Officer in liaison, communication, and interpretation of suggestions and criticisms. The responses to presentations of information often assume the guise of advice and direction. Even when advice is sought or required, it is often conflicting or out of touch with evolving needs and goals.

Recommendation: The Toxicology Information Subcommittee should initiate and agree upon a plan for the development of LADB over a finite period. Administration of LADB should be left to the responsible NLM/LADB staff.

Evaluation of specific portions of the LADB project should be initiated and coordinated by the TIS/LADB Task Group and the NLM/LADB staff. The frequency of external evaluation of the entire project should be reduced. In the past, frequent evaluations have led to conflicts between goals and frequent
reorientation of program direction. The TIS should include in its development plan a schedule for review and evaluation of the major activities and the overall project only every two or three years.

B. STAFF COOPERATION

The pattern of staffing LADB by both the NLM and BCL has contributed to unevenness in production and cooperative efforts. Only two positions at SIS/NLM are permanent positions designated as LADB staff; the other two positions are on loan to the project by other DHHS agency units. Similarly, BCL staff involves from 25 to 58 persons who devote 1830 hours per months or 12 full-time equivalents to the project. The major BCL staff emphasis in project management, information processing, and veterinary pathology involves at least six persons. Despite the heavy investment in personnel by BCL, the sheer number of individuals involved on a part-time basis tends to blur lines of communication and responsibility internally. The Panel observed that cooperation between any two groups, regardless of function or purpose, is compromised when the size of both groups fluctuates and when there are no clear, delineated, and firm guidelines with respect to leadership and responsibilities.

The Panel also questioned how effectively the NLM/LADB and BCL staff persons were contributing to the administration and development of LADB. Because both organizations have excellent reputations, there was concern that a problem may exist regarding the coordination of efforts by the two staffs responsible for LADB. Both staffs seem to have developed a defensive posture regarding criticism, even when such criticism appears warranted.

Recommendation: The diffuse nature of project direction is partially attributable to the evolution of leadership patterns and the lack of coordination between the NLM and BCL staffs assigned to the LADB Project. The current situation could have been predicted given the nature of NLM staff appointments and the complexity of the BCL staff involvement. However, the Panel concluded that such problems can be resolved by extensive and logical commitment to planning. Thus, the Panel recommends that a plan of action covering the next three years of LADB activity must be developed.

The LADB Project Officer must provide leadership and direction for the achievement of specific goals in a reasonable time frame. The Project Officer must develop and communicate a reasonable plan for further implementation of LADB goals and must hold to this framework. The Project Officer should be assisted by a professional and support staff whose abilities and duties are consistent with the major thrust of data acquisition.

Similarly, the BCL/LADB Project Manager must be given detailed and explicit written directions regarding tasks and deliverables each month or quarter. Quarterly reviews of BCL performance should be based on critical analysis of written records of task performance and deliverables rather than assessment of progress toward major contract goals. On the other hand, a more dedicated commitment from the management of BCL is consistent with greater assumption of responsibility and accountability. To this end, BCL should
consider the assignment of certain personnel to the LADB Project on a full-time basis. The BCL/LADB Project Manager must have the administrative authority to marshall the broad array of BCL expertise to meet LADB needs efficiently and expeditiously.

The first priority with respect to NLM/LADB staff modification must be the permanent appointment of a contact-scientist, with credible standing in the scientific community, to work full-time on data acquisition since this task is of utmost importance to the success of LADB. The creation of permanent positions for NLM/LADB staff appears necessary to assure continuity and security for both project and personnel.

The failure to deliver items promised to public users damages the reputation of the BCL/LADB staff, and inculcates a negative attitude toward LADB in general. The new "User Manual" must be made available immediately and not significantly changed for a predetermined time, the "Newsletter" and "Table of Contents" must be delivered at regular intervals, on-line news must become a regular feature, and a certificate of training course completion must be sent to the trainee within a reasonable time after the session is completed.

The Library cannot expect to attract LADB users unless a coordinated public relations campaign is initiated to allow prospective users to observe what LADB has to offer. The publication of articles in scientific journals on the content, application, and usefulness of the database should be part of such a campaign. The ultimate value of LADB demands that this unique source of quantitative data be fittingly promoted.

The Panel notes with some concern that the monthly publication, "The NLM Technical Bulletin" has yet to contain information on the April 1980 public availability of LADB. This publication does contain information on total records and searching techniques for other NLM on-line, as well as other new and experimental, databases. "The NLM Technical Bulletin" is a widely distributed and highly regarded source of information on NLM computerized literature and data sources; as such, it is an ideal document to provide information about LADB to potential users.

C. ACCOUNTABILITY

The deliverables requested by NLM from BCL as described in the Request for Proposal (RFP) of 22 March 1979 and the subsequent contract require further explanation and embellishment. The "Statement of Work" is an adequate explanation of the objectives of the indicated tasks and the goals to be achieved but, in terms of a working document, it is too general and frequently vague.

Recommendation: The plan for LADB activity over the next three years should use the contract statements as a framework for NLM and BCL cooperative efforts. Contract language must be sufficiently precise to indicate exactly what the NLM/LADB Project Officer expects in terms of major activities, progress required,
and specific deliverables. For each major task outlined under contract deliverables, the level of effort should be designated. With these contract modifications in place and acceptable to both parties, BCL must be permitted to follow through on the indicated tasks without continued ad hoc modification of tasks by the NLM/LADB staff.

With the implementation of a plan such as the one outlined above, BCL is aware of what is required, as well as how and where it is expected to allocate efforts and funds. In turn, NLM then has a reasonable means for measuring contractor performance in terms of quantifiable goals.

D. ADMINISTRATIVE TRANSITION

The Panel concluded that while NLM has taken the leadership in development of LADB, the ultimate utility of the system will be more closely associated with other government agencies and institutes, such as NIH, NTP, EPA, FDA, and USDA, which have legislatively mandated responsibilities that involve genesis of and actions based on data derived from animal experimentation. However, the Panel also determined that LADB is not yet sufficiently developed to be separated from the NLM/SIS programs. While the ultimate administrative responsibility for LADB is vested in the Toxicology Information Subcommittee of the DHHS Committee to Coordinate Environmental and Related Programs, NLM has managed LADB since its inception and should continue to do so. Though there have been, and continue to be, certain deficiencies in administration, management, and performance that were evident to the Panel, none are insurmountable obstacles to building a database which meets perceived user needs.

Recommendation: Prior to April 1981, the LADB Task Group and NLM/LADB staff should develop a reasonable plan for transition of LADB from the public to the private sector over the next three years. This plan should be based on the primary goals of enlarging LADB by aggressive efforts at acquisition of rodent data (as noted above) and of making the individual animal data files available on-line. The transition plan should be developed within the next several months; it should have input from the BCL staff and carry the imprimatur of the TIS/LADB Task Group. The plan should be based on a transition of LADB from the public to the private sector over the next three years, but should include provision for control of data acceptance criteria by a designated Federal organization such as NLM, as well as a system for peer review of submitted data. Such a plan would provide a firm foundation for:

1) developing a broader base of Federal agency and institute support currently, but with agreed upon finite and predetermined withdrawal of public funding;

2) establishing a recognized incentive for the vendor to assume greater responsibility, as well as greater potential gain; and

3) evolving a scheme for increasing user costs, as benefits from the increased scope of LADB enhance its value to the user (such a scheme may well include incentives for user/donors).
During the three-year transition period, NLM has a responsibility for retaining administration of LADB for a variety of reasons. The Library has been the leader in initiating and funding innovative databases, it has been involved in the development of LADB, and it has a vast experience with other databases. Most importantly NLM should maintain responsibility for acceptability criteria and quality control during this phase and after the transfer of LADB to a commercial or other vendor. Therefore, good rapport and a unified, cooperative effort between NLM and the organization designated to assume control of LADB is essential to the future success of the venture.
EPILOGUE

In a talk at the CODATA Conference in Kyoto, Japan, on 8 October 1980, Philip H. Abelson, the distinguished editor of Science, made the following statement which was subsequently printed as an editorial in the 7 November 1980 issue of that renowned journal:

"Electronic storage of digital data is the only feasible means of dealing with information in areas of science where it is produced at such a great rate that placing it on paper would be impractical. In addition, once the massive amounts of data are in machine-retrievable form, they can be processed and analyzed quickly and with a thoroughness beyond human capability."

The appropriateness of this concept is evidenced by the early investment in computerized literature retrieval systems by NLM, as well as the increasingly heavy commitment of various Federal agencies to computerized databases. Despite the difficulties and problems afflicting LADB at this time, Dr. Abelson's statement is applicable to LADB as a model of a unique database with considerable potential to biological and medical research.
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LABORATORY ANIMAL DATA BANK

A new computer-based online information resource is now available—the Laboratory Animal Data Bank (LADB). It was developed by the National Library of Medicine for the Department of Health and Human Services' Committee to Coordinate Environmental Programs and several other governmental agencies.*

The Laboratory Animal Data Bank provides biomedical investigators with rapid access to information and base-line data on laboratory animals. The data bank contains information collected from control animals on hematology, clinical chemistry, pathology, environment and husbandry, and growth and development.

Through the use of LADB, a scientist may (1) select and examine normal values for various physiologic and biologic measurements; (2) determine the environmental and husbandry conditions for each animal group selected; (3) evaluate spontaneous pathologic changes in animals; (4) statistically analyze the data received as distributions (e.g., histograms and scattergrams), as tables, or as complete printed reports.

LADB contains information from over 500 animal groups composed of 30,000 animals, representing 65 strains or species of animals. About one million observations are recorded in the data bank. Information is continually being added and is voluntarily contributed by the pharmaceutical industry, government agencies, and institutions throughout the United States.

There are two types of LADB users—offline and online. The offline user telephones the LADB Search Center in Columbus, Ohio, and requests a search on a subject of interest. The completed report, with explanations, is sent by mail to the requester. The charge ranges from $50 to $250, depending on the complexity of the request, the amount of information desired, and the type of professional assistance needed. The online user has direct access to the computer by telephone via TYMNET. The cost per hour is $20. LADB is not part of the National Library of Medicine's MEDLARS/MEDLINE network, but the user agreements and billing of charges are similar.

Computer services are provided by Battelle Columbus Laboratories under a contract with the National Library of Medicine.

For further information on the availability of LADB call or write:

LADB Project Office
National Library of Medicine
Building 38-A, Room 45-408
Bethesda, Maryland 20209
Telephone: (301) 496-5023

*National Cancer Institute, National Center for Toxicological Research, Environmental Protection Agency, and the Interagency Regulatory Liaison Group.
THE LABORATORY ANIMAL DATA BANK

This document is a synopsis of information on the concept, development, current status, and evaluation of the Laboratory Animal Data Bank (LADB), prepared as background information for the Life Sciences Research Office ad hoc LADB User Assessment Panel II Meeting on 20–21 November 1980. Information in this paper and the expertise of the Panel members will serve as the basis for discussion of those topics identified in Section V.

I. BACKGROUND AND CONCEPT (Hoag, 1980; Omni Research Incorporated, 1975)

The Laboratory Animal Data Bank (LADB) was started in 1974 as a project of the NLM–chaired Toxicology Information Subcommittee (TIS) of the Department of Health and Human Services (DHHS) Committee to Coordinate Environmental and Related Programs. All the projects of this Subcommittee are managed by the National Library of Medicine (NLM). LADB is the largest and most complex of these projects.

More than 26 million animals are used annually in biomedical research and testing. Rarely is a single animal used in more than one experiment. Once the results of an experiment have been published, the data usually are retained or stored but are not readily available to the research community. LADB was conceived as a repository for these data from unmanipulated control animals which would allow national dissemination of this information through a computerized, on-line search and analysis system.

Because these data are collected under a variety of conditions, it is essential to include in LADB detailed descriptions of the environment and management conditions under which the animals were kept. Much of the initial effort in the development of LADB was devoted to the identification of a set of environment and management factors that might influence the biological responses of the animals. About 120 such factors have been selected for inclusion in the data bank.

Biological measurements common to animal research have been identified and constitute the classes of data that are represented in LADB. These include: growth and development, clinical chemistry, hematology, and pathology.

A computerized on-line retrieval and analysis system using the BASIS (retrieval) and SPSS (statistical analysis) software has been constructed. The system is designed so that the bench scientist can retrieve and analyze LADB data with a minimum of training.

The major objectives of LADB (National Library of Medicine, [Undated]) are:

- To assist researchers in reaching decisions on the most suitable species and strain of laboratory animal for a particular experiment;
- To provide comparisons of laboratory data grouped according to strain, source, environmental factors, husbandry factors, and test methods used;

- To establish accurate baseline values considering similarities of animal groups with regard to the factors outlined above;

- To determine factors which might affect test results;

- To determine prevalence or incidence of spontaneous disease conditions and pathologic changes in various strains and species of laboratory animals and determine how these are influenced by the factors outlined above; and,

- To assist in designing experimental protocols with better economy of animals, manpower, and equipment.

II. DEVELOPMENT OF LADB (Altman, 1980; Battelle Columbus Laboratories, 1978a)

In July 1975, the National Library of Medicine contracted with Battelle Columbus Laboratories (BCL) to develop and implement the LADB. During the initial 3-year contract period, the following tasks were achieved:

1. Implementation of a plan for building the data bank using a modular design;

2. Development of a data element definition system;

3. Production of a working system for solicitation, collection, and evaluation of control animal data in experimental use; and,

4. Implementation of a data file design allowing interactive usage by biological scientists not trained in computer science.

After completion of these tasks, a Request for Proposal was initiated in March 1979 for the "Continued Development of the Laboratory Animal Data Bank". The objectives of this award fee contract were to:

1. Enrich and maintain LADB, with particular emphasis on increasing data collection and stringent data quality control based on the advice of peer advisory groups;

2. Make this interactive system publicly available;

3. Pursue a research and development program to improve, expand, and augment the system's capabilities in terms of the full range of system and service functions and in relation to the relevant aspects of hardware, software, scientific content, and human engineering.

BCL was awarded this 3-year contract, commencing in September 1979.
III. CURRENT STATUS OF LADB (Hoag, 1980)

A. Data Input

Data are contributed to LADB voluntarily by industrial, academic, and governmental laboratories. However, the data acquisition effort has been difficult. Out of several hundred potential donor organizations contacted, only 60 have actually contributed data up to this time (see Table 1). Data are stored on the basis of species, strain, and substrain. The present content of the database, by species, is shown in Table 2.

On-line access has been available to the scientific community since March 1980. The file available for on-line searching contains summary data derived through processing of the individual animal data obtained from the donor organizations. It is intended also to make an on-line Individual Animal Data File available to the public in the near future.

B. Hardware

The LADB summary data file is resident in a Cyber 73 computer at BCL, and national access is provided through the TYMNET® communications network.

C. Usage

Training and other user support services (e.g., trouble desk, technical bulletin, user manual) are provided by BCL under the contract. Some 65 persons representing 47 institutions have been trained as of 15 October 1980 in eight, 2-day training classes.

At this point, it appears that scientists and subscriber institutions are using LADB for the following purposes:

1. To determine expected ranges of data values under various environmental conditions as a basis for choosing the minimum sample size for experimental design;

2. To investigate species and strain-dependent characteristics;

3. To determine spontaneous tumor incidence and normal biologic responses under specific environmental conditions;

4. As a medium and mechanism for exploring relationship between environment and biological responses; and,

5. As a comparison of test methods and the expected variability of the responses.
D. Charges

Users are charged $20/hour for access and communications, with a $20/month minimum charge. Charges are collected for NLM by the National Technical Information Service under an agreement similar to that covering the billing and charge collection for other NLM services.

Users can also avail themselves of an off-line service through which custom searches are performed by BCL staff. These searches are charged at $50 to $250 depending on the personnel resources required for the response.

E. Funding

Over the years, major funding for LADB has been provided by the National Cancer Institute (NCI) and other government agencies and organizations (see Table 3). Total expenditures for the 6 years 1975-1980 are $3,771,714 or an average of $628,620/year. Of that amount, NCI provided $2,177,000 or an average of $363,000/annum, which constitutes almost 58% of the total support.

F. Program Sponsorship, Administration, and Staffing

The LADB is sponsored by the DHHS Committee to Coordinate Environmental and Related Programs through its Toxicology Information Subcommittee, and is administered by the NLM.

The LADB Staff consists of a veterinary scientist and clerical support provided by the National Library of Medicine, plus two professional positions provided by the National Cancer Institute and one provided by the National Toxicology Program.

IV. EVALUATION OF LADB (Hoag, 1980)

Because of the complexity of developing a database such as LADB and the novelty of many of the issues to be dealt with, it was necessary to establish an outside scientific review mechanism for LADB. A special review committee for an overview of LADB was assembled under a contract with the Institute of Laboratory Animal Resources (ILAR), of the National Academy of Sciences in 1976. This group has issued two reports (1978, 1979) that recommended, inter alia, that a more detailed review mechanism for the content and usage of LADB should be developed.

Accordingly, NLM contracted in September 1978 with the Federation of American Societies for Experimental Biology (FASEB) to establish panels of scientists to review LADB data acceptance criteria and data element utility in the on-line user situation. FASEB created separate panels for: environment and management, hematology and clinical chemistry, growth and development, pathology, and statistics. An interim report by the FASEB group was issued in March 1980, and a final report is due in March 1981.
The Toxicology Information Subcommittee of the DHHS Committee to Coordinate Environmental and Related Programs formed another review panel, the LADB Task Group, staffed mostly with NIH scientists, to review LADB progress and to assist in monitoring the implementation contract.

A. Institute of Laboratory Animal Resources Report I, August 1978 (Institute of Laboratory Animal Resources, 1978)

In June 1976, the NLM requested that ILAR provide advice on certain scientific and technical aspects of the LADB. This work was performed by a Committee on Laboratory Animal Data, which met in 1977 and 1978 to receive reports from NLM and BCL staff, and to respond to specific requests for guidance on various aspects of the development of the LADB.

In response to a second request by NLM staff, the ILAR Executive Committee formed a Panel which in the fall of 1978 completed a general evaluation of the LADB, including its basic concept, purpose, scope, validity, and application, as well as a review of selection and processing of input data, data sources, current status, potential, and work yet to be done.

The major recommendations by the ILAR Executive Committee and its LADB Panel covered the following topics summarized below:

Quality Control — evaluate data source selection, data collection procedures, data element descriptors, as well as data screening and processing;

Scientific Credibility — review criteria for derivation of range-setting standards, validation and rejection of data;

Quantity of Data — consider the amount of data essential to bring the base to optimal usefulness, and to provide statistical validity for the numerous variables being considered;

Animal Species and Strains — examine criteria for species, strains, and animal groups to be included in the data bank if it is to be truly representative of existing laboratory animal populations;

Animal Groups — review criteria as to changes in environment and husbandry required for designating an animal group as a new group; and,

Data Element Descriptors — evaluate data elements on basis of usage, frequency of usage, combinations used, and patterns of usage.

B. Institute of Laboratory Animal Resources Report II, August 1979 (Institute of Laboratory Animal Resources, 1979)

The second evaluation of the LADB Project was completed by the ILAR Committee on Laboratory Animal Data on 31 August 1979. Given the fact that the LADB Program has become a complex, integrated system supported by
multiple agencies, accountable to several review groups, and funded at a level exceeding all previous estimates, the ILAR Committee was of the opinion that strong central management of the project is essential if LADB is to succeed. Answers to the following questions were deemed vital to the resolution of specific management issues:

1. What is the clear statement of LADB program goals?

A number of answers have been given, but it would be well to have a concise, easily understandable statement.

2. Who are to be the beneficiaries of LADB?

A bona fide marketing survey has not yet been done, either in the OMNI feasibility study (OMNI Research Incorporated, 1975) or during the course of developing the LADB program. It has from the outset been assumed that research investigators would be the primary user population, but there is no evidence to support the assumption that substantial numbers of research investigators know about LADB and stand ready to be paying users of the service.

3. What are the priorities and constraints, as seen by LADB, for adding to the program of species, data elements, laboratory (source) contacts, and incentives?

Initially, it was strongly suggested by ILAR that a "pilot plant" concept be adopted. The levels and sources of support and current lines of inquiry experienced by LADB make it fairly obvious that rodents are the primary species of interest. An intensified effort to develop a miniature version of LADB, using one or two species, could have brought to light problems and limitations of the system in its early stages. A somewhat "omnidirectional" approach to gathering data, as well as a propensity to expand into new areas, continuously has weakened the overall program. Without an overall strategy, these new areas continue to grow without critical review. The adequacy of the summary (base-line) file concept is critically dependent on anticipated usage patterns. If the primary use is by determined investigators with relevant experience, little analysis or detail is to be expected. If expectations and needs go beyond this level, the primary data must be analyzable through LADB.

4. What are the milestones for decisions on major system developments?

The question of how much data are adequate for a given species has been posed several times. An overall strategy should underscore the need for answering such a question and should design appropriate studies or inquiries to provide a basis for decision-making.
5. How will LADB evaluate the usefulness of database components?

There is no strategy for finding out what data are not useful, understanding why they are not useful, and purging them from the system. Overall emphasis still appears to be on gathering as much data as possible.

The ILAR Committee also addressed the issue of making the LADB publicly available early in 1980, as follows:

"This important decision has been carefully and repeatedly reviewed by the project management, seemingly on the assurance that earlier problems of data content, technical capacity, and professional field representation have been solved. There is not at present a correspondingly detailed plan to monitor the use of the system by public users and to evaluate carefully their successes and failures, their potential further data and information processing needs, and to identify obstacle (financial or otherwise) in obtaining the benefits of the LADB system. The importance of, and the effort and skills necessary to perform, evaluations of user experiences with an automated information system such as LADB are markedly underestimated by LADB staff."


In response to the recommendations of the ILAR Executive Committee Panel report, the LADB Task Group (a subcommittee of the U.S. DHEW Committee to Coordinate Toxicology and Related Programs) concurred with the necessity for objective peer review of data submitted for inclusion in the LADB, and evaluation of criteria for acceptability of such data (Battelle Columbus Laboratories, 1978b; Cameron, 1978). To accomplish these goals, the NLM negotiated a contract with FASEB to have its Life Sciences Research Office (LSRO) organize an ad hoc LADB User Assessment Panel. This Panel was charged with reviewing data descriptors and disciplinary coverage of the LADB. The goals of the study can be considered as two phases of a single objective:

1. **Evaluation of Criteria** — the LSRO ad hoc Panel has evaluated the existing policies and guidelines for data acceptability, and determined whether submitted data are acceptable for inclusion in the LADB in terms of:
   
a) Data element and descriptor compliance;
   
b) Species, strain, and genotype nomenclature;
   
c) Categorization and/or type of data, including protocol description, etc.; and,
   
d) LADB needs for the amount and type of data under consideration.
2. **Data Acceptability Review** — the LSRO ad hoc Panel, functioning as an initial Data Acceptability Review Group (DARG), is reviewing submitted data in terms of revised guidelines, and on the basis of objective analysis will render a scientific opinion on whether the data should be:

a) Accepted unconditionally;

b) Accepted provisionally with suggestions on needs for clarification, supplementation, etc.; or,

c) Rejected with appropriate explanation.

Since late 1979, each LSRO ad hoc Panel member has had available a computer terminal providing access to the LADB database. The experience gained from personal use, as well as input from use by colleagues, graduate students, and others requiring information related to animal experimentation constitutes an essential portion of the basis for objective assessment of data descriptors and disciplinary coverage.

D. Toxicology Information Program Committee Report, June 1980
(Toxicology Information Program Committee, 1980)

The Toxicology Information Program Committee (TIPCOM) recognized that it is difficult to evaluate the effectiveness of an information retrieval system, such as LADB, that has been publicly available for only a few months. However, the Committee deemed it appropriate to make some comments on the LADB concept and several recommendations for its evaluation.

Regarding the concept of LADB, the members of TIPCOM have reservations about the proposal that LADB would lead to large savings (a figure of approximately $80 million/year has been suggested) through the more efficient use of control animals. Members of the Committee agreed that few toxicologists would substantially reduce the size of their own controls or trust historical controls from other laboratories. One member of the Committee suggested that most major laboratories already have sufficient access to historical controls for the common species of laboratory animals and that a file like LADB might be more useful for species less commonly used in toxicologic studies and not presently included in the data bank.

The Committee found reasonable the assertion that LADB could be helpful in the selection of appropriate animal models for particular lines of experimentation. A distinct advantage that TIPCOM recognized in LADB was the capability of keeping the file current. LADB would provide information on the status of laboratory animal data as they exist today, whereas handbooks and other sources of information collected on a smaller scale quickly become outdated. The Committee agreed that toxicologists would find the LADB data interesting and that it would provide a reference with which to compare their own data. It was not clear to the Committee, however, whether the advantages of LADB warrant the major expense entailed.
V. ISSUES TO BE ADDRESSED (Hoag, 1980; Toxicology Information Program Committee, 1980)

The NLM Board of Regents and the Toxicology Information Program Committee have recently considered some of the financial and administrative problems confronting LADB. One such issue concerns cost-recovery at a user charge of only $20/hour. Another is the identification of alternative sources of funds for support of the project. A question was raised also as to whether NLM is the proper organization to manage a project such as LADB, and whether the personnel resources are adequate.

A. Utility (Toxicology Information Program Committee, 1980)

Although the utility of LADB remains to be determined, TIPCOM suspects that in many cases its services may be more a convenience than a necessity, and those users who are receiving such services at a cost far less than the cost of providing the service consider it worthwhile only at the minimal price. Efforts should be made to determine the validity of this statement by obtaining answers to the following questions:

1. How well does LADB meet your needs; in what ways do you find it deficient?

2. Do you believe that LADB fulfills its major objectives (stated in "Background and Concept", see page A-3)?

3. Has the use of LADB resulted in a saving of time, animals, manpower, or equipment?

4. Does LADB contribute more than an extensive historical database; does it provide a means for selecting appropriate animal models, for improving experimental design, and for permitting statistical analysis of data?

5. Would you subscribe to LADB if the hourly on-line rate were doubled or tripled?

6. What suggestions, specific and general, would you make for the improvement of LADB?

B. Cost-Effectiveness of LADB (Hoag, 1980)

As an information project, LADB is costly and questions as to its cost-effectiveness have been raised. While user charges, at the $20/hour level, pay for the computer and communications costs connected with searching, they do not, of course, pay for maintenance of the database itself. Therefore, there is a basic question as to the level of government support that ought to be provided for a database serving only a limited community, albeit for very expensive purposes—animal testing.
C. Funding and Funding Sources (Hoag, 1980)

For the past 6 years, the National Cancer Institute (NCI) has been the major source of funding for LADB (see Table 3). However, NCI has indicated it may not provide funds for the project in fiscal year 1981. This decision was not based on a negative assessment of the LADB, but rather on a belief by NCI management that other NIH organizations with a stake in animal research and testing should contribute to the maintenance of the project. Currently the National Toxicology Program (NTP) is the organization that sponsors most animal testing in the Department of Health and Human Services. A request for funds has been made to NTP, but it has not been acted upon to date. Additional sources of funding to support the program must be considered.

D. Program Sponsorship, Administration, and Staffing (Hoag, 1980; Toxicology Information Program Committee, 1980)

A question has been raised as to whether the NLM is the proper organization to manage a project such as LADB. The Toxicology Information Program Committee (TIPCOM), however, expressed its support of LADB as a part of the programs of the TIPCOM at NLM as follows:

"LADB is appropriate for the NLM, in that it is an information activity with relevance for toxicology and the biomedical sciences. NLM has the experience and capability in handling scientific information that a database like LADB requires. Although one cannot conclude that no other institution would have been suitable to house LADB, some of the experience gained at NLM would certainly be lost if LADB were moved elsewhere. It is logical, of course, that those agencies that would make greatest use of LADB be sought to contribute proportionately to its upkeep. It also seems important that, as long as a large proportion of the work on LADB is done by NLM contractors (i.e., Battelle Columbus Laboratories), NLM should maintain complete control and responsibility for the activities of the contractors."

The LADB Staff consists of three veterinary scientists, an information scientist, and a secretary. Is such a small staff adequate to handle the requirements of the program?
VI. LITERATURE CITED


Battelle Columbus Laboratories. 1978b. Data quality assurance for the Laboratory Animal Data Bank. Prepared for the National Library of Medicine. [93p.] Available from: Battelle Columbus Laboratories, Columbus, OH.

Cameron, T., Acting Chairman. 1978. LADB Task Group, DHEW Committee to Coordinate Toxicology and Related Programs. Letter, dated October 30, to C. Morgan, National Academy of Sciences, Washington, DC.

Hoag, W.G. 1980. Specialized Information Services, Toxicology Information Program. Presentation (dated September 1980) to National Library of Medicine Board of Regents on October 9, Bethesda, MD.


LABORATORY ANIMAL DATA BANK
CONTRIBUTORS OF DATA

I. Organizations Voluntarily Contributing Data

Argonne National Laboratory
Battelle Northwest Labs
Bristol-Myers Products
California Regional Primate Center
California, University of, Berkeley--Animal Resources Division
California, University of, San Diego
Canadian Environmental Health Centre
Carnegie Mellon
CIBA-GEIGY
Colorado State University
Dow Chemical (Indianapolis)
Dow Chemical (Midland)
EPA--Research Triangle Park
Eli Lilly
FMC Corporation
Fort Detrick (USAMRIID)
G.D. Searle
Haskell Labs
ICI America
IITRI
Jackson Labs
Johnson & Johnson
Marshall Research Animals
McGaw Labs
McNeil Labs
Mead Johnson
Microbiological Associates
Midwest Research Institute
NCI--Animal Resources Branch
NCI--Carcinogenesis Branch
National Center for Toxicological Research
National Institute on Aging
New York University
National Institute of Environmental Health Sciences
Northern Iowa, University of
Norwich-Eaton Pharmaceutical
Ohio State University
Oregon Regional Primate Center
Procter & Gamble Company
Roswell Park
Smith, Kline & French
Squibb Institute
Standard Oil of California
SYNTEX Labs
II. Contractors Directed by the Government to Contribute Data

Alton-Ochsner Foundation
Battelle Columbus Labs
California, University of, San Francisco
Dow Chemical (Indianapolis)
Gulf South Research Institute
Hazleton Labs
IITRI
Litton Bionetics
Mason Research Institute
Midwest Research Institute
New York University
Ohio State University
Papanicolaou Cancer Research Institute
San Francisco, University of
Southern Research Institute
Stanford Research Institute

III. Recent Contributors Who Had Previously Promised Data

Bowman Gray School of Medicine
Charles Pfizer
Merck Institute
Monsanto Environmental Health Laboratory
Pharmacopaths
Schering-Plough (Lafayette, N.J.)
Taconic Farms
WPAFB (Aerospace Medical Research Lab)
Wyeth Labs
### LABORATORY ANIMAL DATA BANK

**DATA CONTENT**

<table>
<thead>
<tr>
<th>Type of Animal</th>
<th>No. of Animals</th>
<th>Clinical Chemistry</th>
<th>Hematology</th>
<th>Growth</th>
<th>Organ Weight</th>
<th>Pathology</th>
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<tr>
<td>Cat</td>
<td>190</td>
<td>---</td>
<td>2,518</td>
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<td>Dog</td>
<td>5,610</td>
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<td>191</td>
<td>178</td>
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<td>30</td>
<td>955</td>
<td>910</td>
<td>74</td>
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<td>24,665</td>
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<td>47,635</td>
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<td>Tree Shrew</td>
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<td>127</td>
<td>381</td>
<td>31</td>
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**TOTAL:** 27,313 181,483 318,018 102,692 32,006 259,709

**TOTAL OBSERVATIONS:** 893,908
FUNDING FOR THE LABORATORY ANIMAL DATA BANK

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<th>Supporting Agency</th>
<th>NLM</th>
<th>NCI</th>
<th>OASH(7)</th>
<th>FDA (NCTR)</th>
<th>IRLG(8)</th>
<th>OD/NIH</th>
<th>EPA</th>
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<td>FY 1975</td>
<td>11,694</td>
<td>270,000</td>
<td>103,112</td>
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<td></td>
<td></td>
<td>384,806</td>
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<td>100,000</td>
<td>83,000</td>
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<td>520,000</td>
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<td>FY 1977</td>
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<td>330,000</td>
<td>100,000</td>
<td>93,544</td>
<td>25,052(2)</td>
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<td></td>
<td>647,064</td>
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<td>190,694(4)</td>
<td>237,000</td>
<td>100,000</td>
<td>47,000</td>
<td>50,000</td>
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</tr>
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<td>100,000</td>
<td>50,000</td>
<td></td>
<td>100,000(6)</td>
<td></td>
<td>945,150</td>
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<td>FY 1980</td>
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1. Feasibility Study
2. ILAR/NAS Review Contract
3. Purchase of BASIS software and online services
4. FASEB - $155,544
   National Academy of Sciences (NAS) - $28,265
   Battelle Columbus Laboratories (BCL) - $6,885
5. FASEB - $15,150
   New BCL - $150,000
6. End of year failure of funds transfer mechanism resulted in returned funds to EPA; funds provided by NLM instead.
7. DHHS Committee to Coordinate Environmental and Related Programs funds are obtained from the Office of the Assistant Secretary for Health (OASH).
8. Interagency Regulatory Liaison Group (IRLG).
### DATA AVAILABLE IN LADB

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* data not available  
** pre-experiment and quarantine animal data removed

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* One organization is reported both as a donor and a source.
† All Carcinogenesis Bioassay Data System (CBDS) data have been reported in 1980 although received much earlier, then deleted, and restored. Some early data were not restored and some additional data were added in 1980. There were 6 data donors, 258 animal groups, and 9829 animals added in 1980 for CBDS data.
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| TOTALS | 3 | 9 | 1 | 4 | 14 | 4 | 5 | 9 | 4 | 6 | 11 | 1 | 2 | 4 | 13 | 2 | 22 | 6 |

APPENDIX V
LABORATORY ANIMAL DATA BANK ON-LINE USAGE

= non-billable

= billable

MINUTES x 1,000

May June July Aug Sept Oct
1980

\[ Y_1 = b_0 + b_1 X_1 \]
\[ b_0 = 903 \]
\[ b_1 = 62 \]
\[ Y_1 = 903 + 62 (X_1) \]
\[ Y_1 = 965 \]
\[ Y_2 = 1027 \]
\[ Y_3 = 1089 \]
\[ Y_4 = 1151 \]
\[ Y_5 = 1213 \]

REGRESSION LINE FOR LADB ON-LINE BILLABLE USAGE
MONTHLY EXPENDITURE -- LADB CONTRACTOR

Task 1: Data acquisition
Task 2: Public use
Task 3: Research & development

Administration/Travel

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* Date system made available to public users
MEDLINE April 1972 to March 1973

HEALTH November 1978 to September 1979

LADB April 1980 to October 1980
TOXLINE April 1974 to March 1975

CHEMLINE April 1974 to March 1975

LADB April 1980 to October 1980

FIRST 12 MONTHS OF PUBLIC USE