

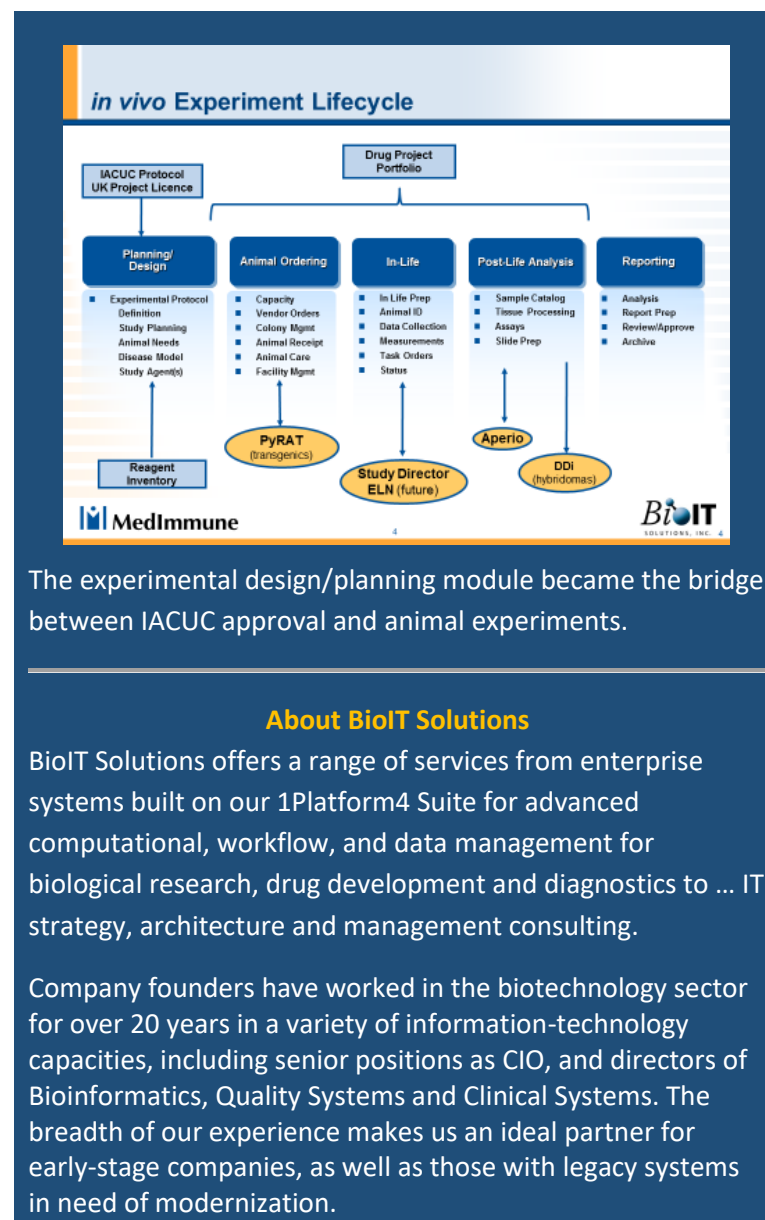
### Challenges

MedImmune, the global biologics research and development arm of AstraZeneca, recognized that their IACUC review and approval process was inefficient. Moreover, the review and approval backlog lacked visibility; lengthy delays were experienced in protocol approvals and project schedules; preparation of the annual inventory of animals ordered and their disposition was difficult.

Issues surrounding the IACUC review and approval process, particularly long approval cycles and the preparation of the annual animal inventory, pointed to deficiencies in the overall process for managing *in vivo* research projects – from experimental planning/design to management of daily vivarium tasks:

- The *in vivo* experimental design/planning process was not integrated with the IACUC review and approval process. This created issues with the preparation of the annual animal inventory report.
- The various software packages, e.g., StudyDirector, operated independently and were not integrated into the overall management of research projects.
- Word documents were used to generate experimental protocols. The vivarium lab manager created a weekly task schedule in a lengthy Word document and taped it to the door of the vivarium. This took all day to complete, it was insensitive to changes, the visibility of the schedule was limited, and some tasks fell through the cracks.
- Different organizations – functional areas and locations – were involved. Coordination and communication across these organizations was difficult. The system was required at research sites in Maryland, California and the UK, with appropriate adaptations needed for each site.

With about 100 protocols submitted annually for IACUC approval and a robust pipeline of preclinical projects requiring *in vivo* studies, MedImmune engaged BioIT Solutions to help address these challenges. A team composed of representatives of the various organizations was assembled, and a situation analysis was conducted.



The experimental design/planning module became the bridge between IACUC approval and animal experiments.

### About BioIT Solutions

BioIT Solutions offers a range of services from enterprise systems built on our 1Platform4 Suite for advanced computational, workflow, and data management for biological research, drug development and diagnostics to ... IT strategy, architecture and management consulting.

Company founders have worked in the biotechnology sector for over 20 years in a variety of information-technology capacities, including senior positions as CIO, and directors of Bioinformatics, Quality Systems and Clinical Systems. The breadth of our experience makes us an ideal partner for early-stage companies, as well as those with legacy systems in need of modernization.

## *In Vivo* Research Management System

### Actions

Working with team members, BioIT created and deployed an *In Vivo* Module for MedImmune’s Research Management System (RMS) that included:

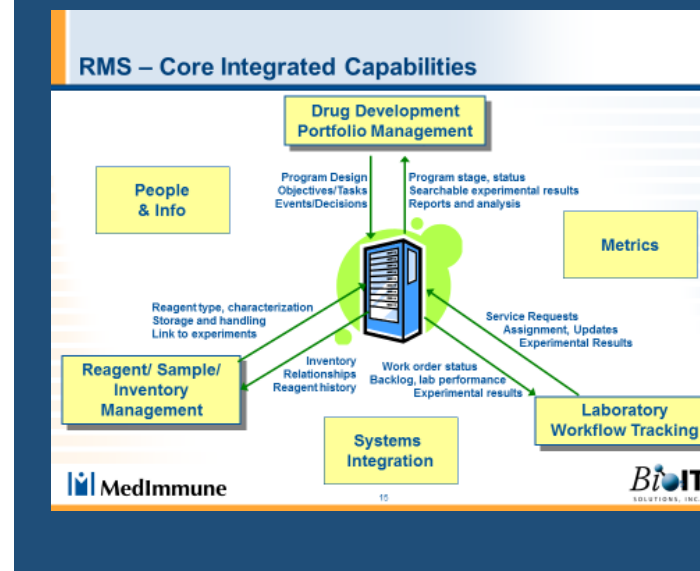
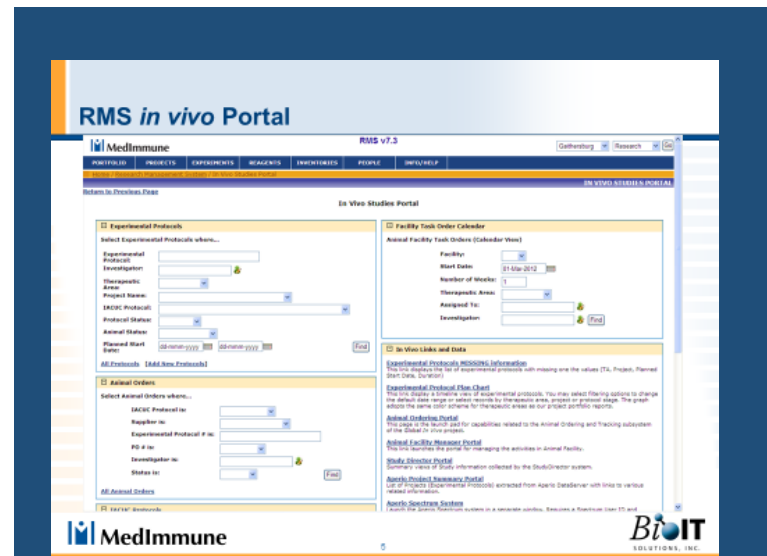
- An RMS-*In Vivo* portal – the gateway to management of in-life studies
- An IACUC portal and dashboard accessed via the RMS-*In Vivo* portal
- An experimental design and planning module that linked IACUC review and approval with experimental protocols and animal ordering
- An animal ordering portal accessed via the RMS *in vivo* portal

The RMS-*in vivo* system also:

- Integrated existing software
- Integrated study management and post in-life analysis/reporting with upfront planning functions
- Replaced paper-based methods for IACUC review/approval and experimental design/planning
- Linked to other R&D management functions, e.g., portfolio management

### Results

Objective	Results
Traceability	Enabled quick, reliable and accurate traceability of biomaterials and results from animal studies
Visibility	Provided visibility for the status and results of <i>in vivo</i> experiments during the lifecycle of a study
Analysis & Reporting	Simplified the procedures for assembling and interpreting results with reports, on-line views, and navigation aids
Process Improvement	Automated steps involved with sample preparation, inventory management, and workflow tracking
Consistency	Encouraged consistency of procedures, nomenclature, inventory management and reporting for <i>in-vivo</i> studies
Integration	Built on investments in software and instrumentation



## Experimental Design and Planning

### Actions

- BioIT created an experimental design and planning submodule as part of the RMS-*In Vivo* module. This submodule incorporates animal ordering and vivarium task planning along with a facility management portal.
- Task management incorporates a calendar with daily and weekly views along with a task detail view.
- The experimental design/planning workflow with integrated approval steps is the bridge between animal ordering and IACUC approval.

### Results

- Increased visibility of experiments and their status
- More efficient – less time consuming planning for in-life studies
- Improved tracking and allocation of resources

## In-Life Studies and Post In-Life Analysis

### Actions

- Vivarium staff can view daily tasks on wall mounted monitors in the vivarium. Touch screens are used to update the status a tasks in real time.
- Study investigators monitor the progress of their studies to assure tasks are completed in a timely manner. E-mail alerts notify investigators and veterinarians of situations that may need attention.
- The RMS-*In Vivo* module also integrated data analysis and report preparation

### Results

- Enhanced visibility of the status and results of in-life studies
- Improved accuracy and reliability of results
- Streamlined management of task assignments, animal inventory, and workflow
- Simplified interpreting results and creation of report

The image displays two screenshots of the MedImmune *In Vivo* Research Management Process software interface.

The top screenshot is titled "Animal Ordering Portal (Manager)". It features a summary table "Animal Count by Year" with columns for Year, Animals Requested, Animals Ordered, and Animals Received. Below this is a table of "Requested Orders" with columns for IACUC Protocol #, Experimental Protocol #, Investigator, Expected Delivery, Protocol Status, Animal Status, Species, Strain, Gender, Age, Animals, Protocol Supplier, and Create Order. A third table shows "Animals Available Recent" with columns for Supplier Name, IACUC Protocol #, Experimental Protocol #, Investigator, PIC #, Species, Strain, Gender, Age (in Weeks), Order Date, Order Qty, Total Cost, Status, and Details.

The bottom screenshot is titled "Daily Calendar View" and shows "Animal Facility Tasks". It includes a search criteria section (Facility: LAB, Planned Date: 09-Mar-2012) and a table with columns for Protocol, Task, Investigator, Assigned To, Status, Assign Task, Open Task, and Complete Task. The table lists various tasks such as "PCTU Turnover", "Bleeding with traps", "3 am", "3 pm", "3 pm", "Blood harvest on a 4 hr time point", "Death checks", "Injury", "Document CareTime and #", "Injury", "Document CareTime and #", "Body weights Obs", "Administration of 25 and 10", "New collection tubes", "30 min", "Collect urine", and "Body weight".

Both screenshots include the MedImmune logo and the BioIT SOLUTIONS, INC. logo.

## IACUC Review and Approval

### Actions

- BioIT created an IACUC submodule and entry portal as part of the RMS-*In Vivo* module and revamped the IACUC review and approval process.
- All IACUC information was captured in a database - no more Word documents.
- The experimental design/planning process bridged the gap between IACUC review and approval and animal ordering.

### Results

- Improved the efficiency of the IACUC review and approval process
  - Average protocol approval time decreased from 85 days to 26 days
  - Average amendment approval time declined from 23 days to 7 days
- Streamlined the process of preparing the annual report on animals by integrating:
  - An on-line review and approval process used by IACUC committee members
  - The IACUC process with experimental design/planning
  - The experimental design/planning process with the animal ordering process
- Clarified what was expected of investigators seeking IACUC approval
- Enhanced visibility of the IACUC process which allowed better management of the backlog of protocols submitted for review and approval
- In the United Kingdom, the system was adapted to track studies by Project License and provide information for annual animal usage reports

The screenshot displays the 'IACUC Portal and Dashboard' interface. It features several key components:
 

- IACUC Protocols by Area:** A bar chart showing the number of protocols across different areas: Behavioral, Genetic, Other, and Strategic.
- IACUC Protocols by Status:** A bar chart showing the number of protocols across different statuses: Withdrawn, Approved, Amended, Expired, and Withdrawn.
- IACUC Protocol Expirations:** A scatter plot showing the number of protocols expiring over time, with a 'Target Date' indicated.
- IACUC Reference Documents:** A section providing links to various documents, including the 'RMS IACUC Portal Reference Guide' and 'RMS IACUC Portal Training Checklist'.
- IACUC Protocols Search:** A form for searching protocols by investigator, protocol title, and status.

**BioIT Solutions 1Platform4™ Suite**

The 1Platform4 Suite integrates multiple scientific and business processes into a single web-based application. The suite consists of a software foundation on which various highly configurable modules are assembled and tailored to each client's specifications and needs. 1Platform4 also includes integration tools for connecting to external systems and laboratory instruments.

- User-defined workflow modules transform complicated tasks into routine activities.
- Complex processes are managed without custom software, adapting to each client's scientific and business practices.
- Easily and rapidly deployed solution based on widely supported technologies (SQL Server, Microsoft ASP.NET, web browser access).
- System hosting by BioIT Solutions ensures data integrity and security without customer-supplied IT infrastructure.