A Collaborative Approach to Public Health Laboratory PHIN-Compliant LIMS Design

2004 PHIN Conference

May 25, 2004

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Presentation Overview

- Purpose – Gary Jones
  - Why did we do this project?
- Product – Anita Renahan-White
  - What did we produce from this project?
- Approach – Pete Kitch
  - How did we accomplish our objectives?

Gary Jones

- Purpose
  - Why did we do this project?

Background

- The critical need for an efficient electronic PHL LIMS became evident after the bioterrorism events following 9/11
- APHL's 2002-05 strategic plan included two key elements:
  - Develop and promote the use of effective laboratory information systems
  - Develop consensus among PHLs and their partners on the essential elements of effective laboratory information management systems

Collaboration

- APHL, the Public Health Informatics Institute, and PHLs partnered from October 2002 thru June 2003 to define LIMS requirements
- Partnership was a successful collaboration of 16 PHLs (15 state PHLs and one county PHL)
- Collaborative initiative showed that a common set of LIMS requirements is feasible
- Collaborative initiative has been an efficient and economically viable manner to address information technology needs
- Collaborative initiative has been a focal point in addressing emerging standards such as PHIN

Benefits

- Recognize current implementations need more than the high level system requirements
- Recognize the value of a common LIMS design as a key component of achieving interoperability
- Recognize the need for detailed design specifications to clearly identify specific functionality needed in a PHL LIMS
- Recognize that vendors and PHLs need a common detailed design to develop a PHL LIMS that is interoperable and follows standards

Future Opportunities

- Collaborative design effort can establish a PHL LIMS “Standard” that can identify future requirements and standards, and continue to drive a common PHL LIMS design
- Collaborative team, with APHL support, has developed a stronger relationship with other public health partners, such as CDC, and can continue as a focal point for PHL LIMS requirements

Anita Renahan-White

- Product
  - What did we produce from this project?

Objective and Scope

- Create comprehensive design for LIMS for PHLs based on the collaboratively developed requirements specifications
- IT Life Cycle Phases include:
  - Planning
  - Analysis
  - Design
- Build on the momentum of the requirements project
- Create a highly valued deliverable (the design specifications) for all PHLs

PHL-LIMS Unique Features List

- Package receiving and handling capabilities
- Ability to handle multiple electronic request formats from the same submitter and report back to the submitter and multiple data requestors in multiple formats
- Emphasis on sample tracking including chain of custody
- Refined aliquot creation and tracking capabilities
- Comprehensive project coding capability including being able to have a single sample linked to multiple projects

PHL-LIMS Unique Features List, cont.

- Multiple domain emphasis (clinical, animal diagnostic, environmental)
- Ability to report seamlessly and easily to a wide range of secondary data users (secondary because they are not test requestors)
- A systematic approach to varied instrument interfaces and data exchange
- The use of a “hybrid” database approach that will enable us to optimize the usage of both “horizontal” and “vertical” database architectures

PHL-LIMS Unique Features List, cont.

- Comprehensive pass through data handling capabilities
- Support for mutual assistance activities (data and results trading, etc.)
- Ability to “link” test sets and associated results across the multiple domains

PHL-LIMS Design Table of Contents

- Laboratory Test Processing (BP #1) Logical Design
  - Test request and sample receiving
  - Test preparation
  - Testing, results recording, and verification
  - Test report preparation and distribution
- Phase 1 Associated Business Processes – Category A
  - Test scheduling
  - Sample tracking/chain of custody
  - Quality control and quality assurance management
  - General laboratory reporting
  - Statistical analysis and surveillance

PHL-LIMS Design Table of Contents, cont.

- Phase 1 Associated Business Processes – Category B
  - Prescheduled tests
  - Inventory control including kits and form management
  - Laboratory mutual assistance/disaster recovery
- Key Master Files
  - Customer master files
  - PHL electronic format library
  - Samples
  - Tests performed
  - Instruments/test methods
  - Laboratorians

PHL-LIMS Design Table of Contents, cont.

- Workgroup Discussion Monograms
  - Phase 1 definition
  - Future phase module descriptions
  - Sample ID
  - Project definition
  - Animal diagnostic laboratory comparisons
  - Electronic data exchange
  - Statistical reporting
  - HIPAA security
- Appendices

Pete Kitch

- Approach
  - How did we accomplish our objectives?

PHL-LIMS Design Approach

- Recycling concepts

  HL7 Messaging is an electronic card deck without the 80 column restriction (plus you don't need a needle if you drop an electronic HL7 message)

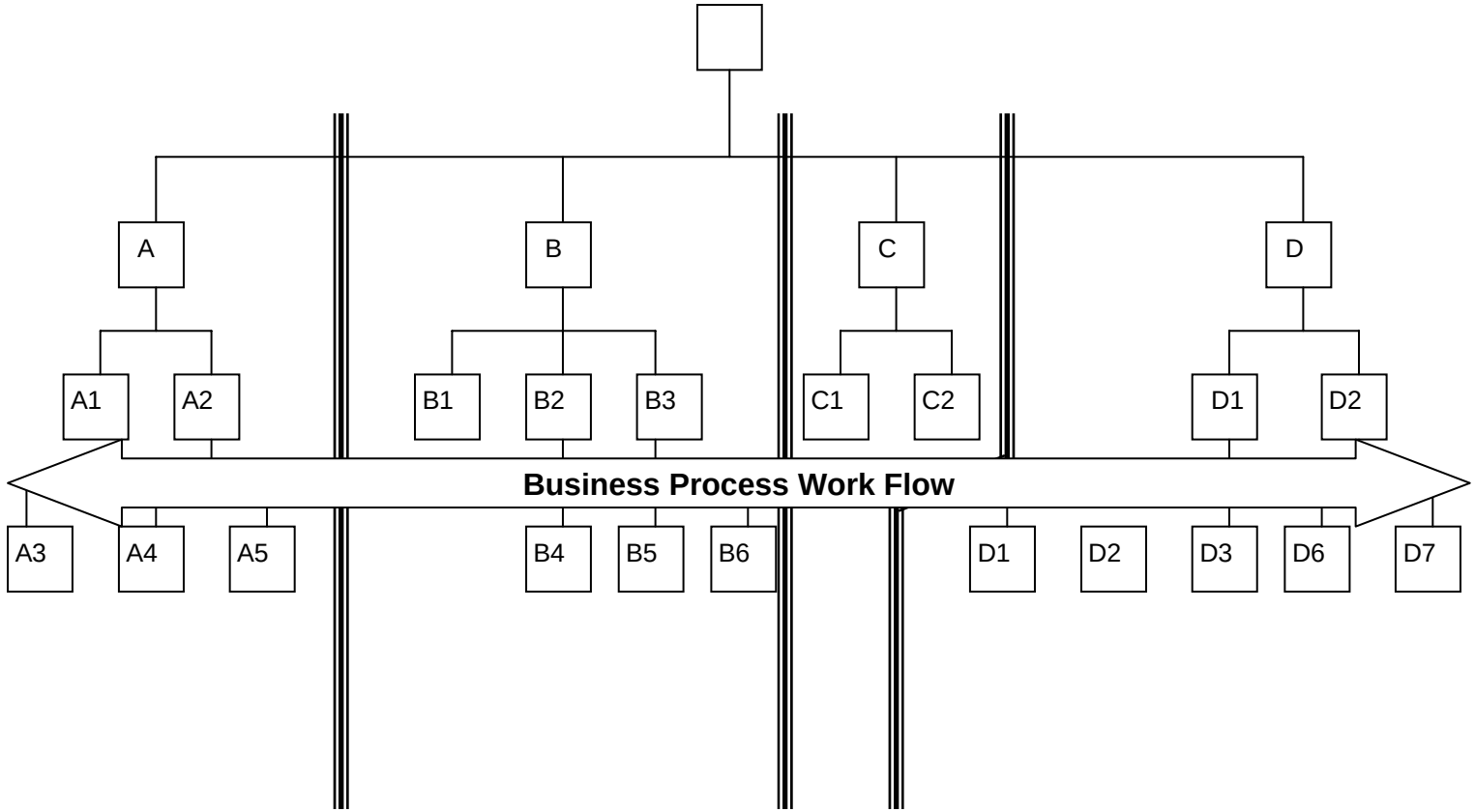
- Methodology impacts on results process versus data modeling

- Communication between users and developers is the age old problem

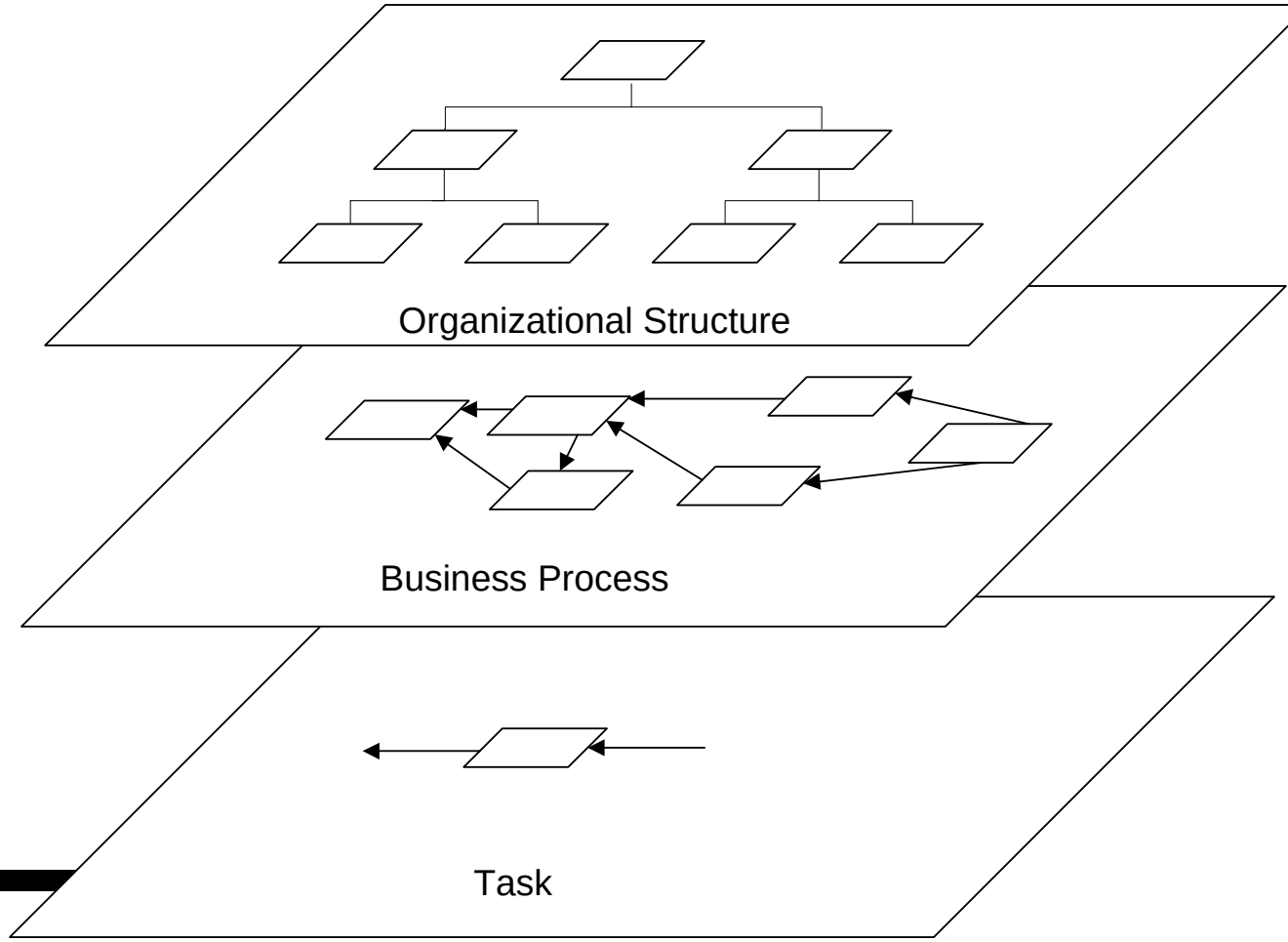
PHL-LIMS Design Approach, cont.

- Development as a logical progression of activities versus iteration or decomposition
- Jigsaw puzzle approach – define the boundary and fill in the middle theme by theme or color by color (the sky first?)
- From business process to programming

PHL-LIMS Design—Business Processes



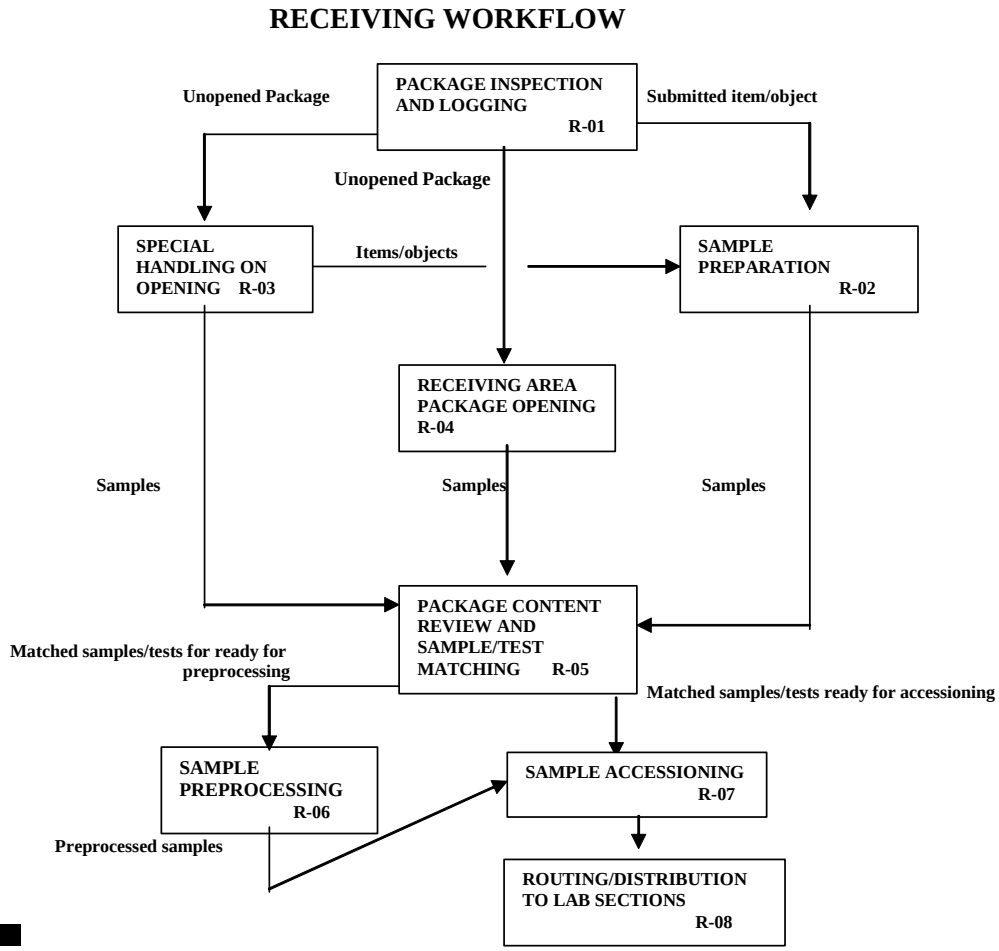
PHL-LIMS Design—Business Processes, cont.



PHL-LIMS Design—Requirements Definition

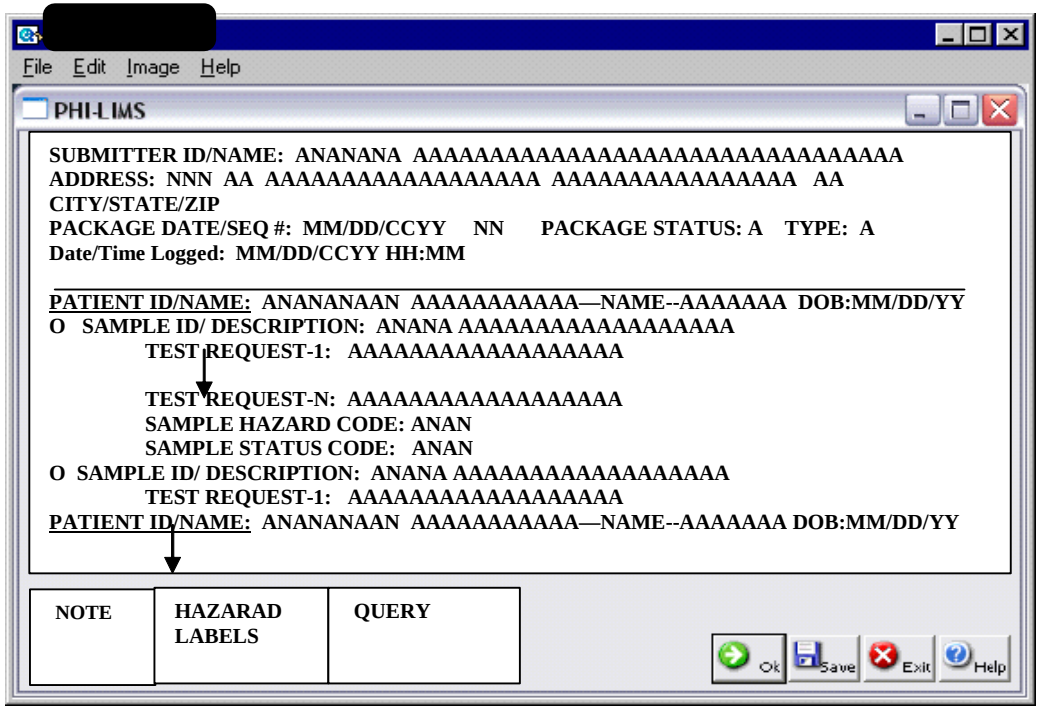
- Context diagramming
- High level business process workflow
- Defining information system project boundaries
- A word about business process re-engineering:
  - Impact of information system on workflow
  - Re-engineering as a mechanism for improving performance and productivity
  - “We’ve always done it that way” syndrome
  - Changing the way in which work is done

PHL-LIMS Design—Details
Work Flow Description



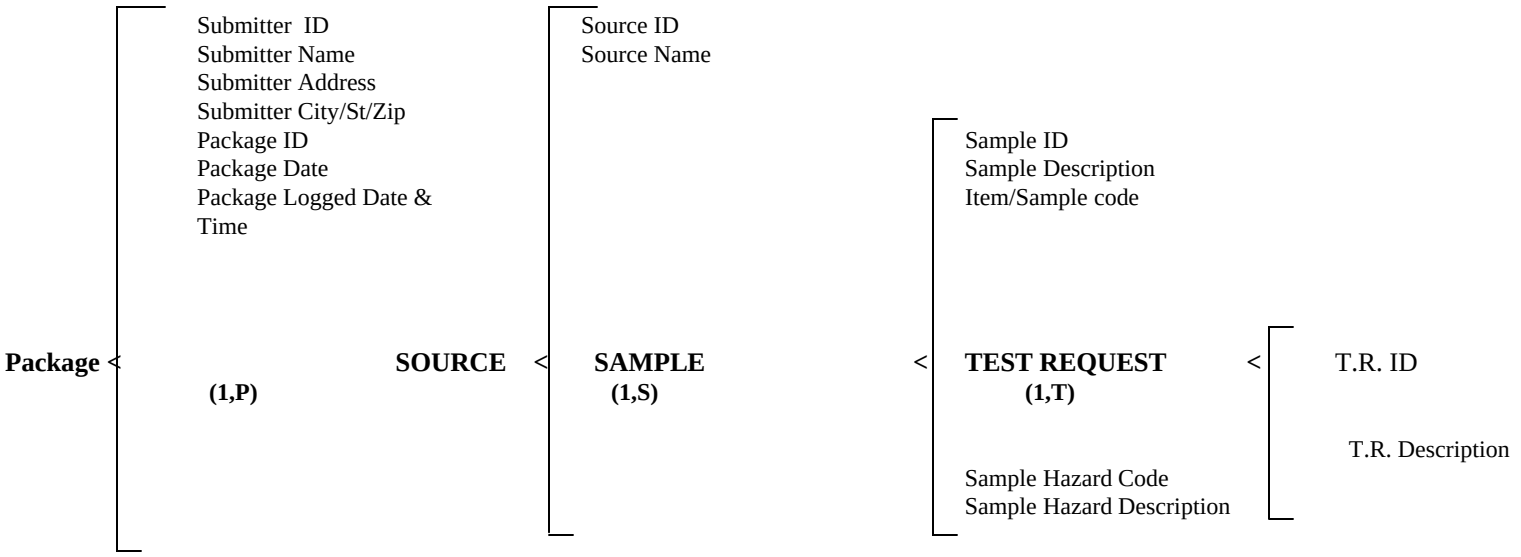
PHL-LIMS Design—Details
Logical Screen Designs

(Patient Sample Example)



PHL-LIMS Design—Details
Logical Data Structures

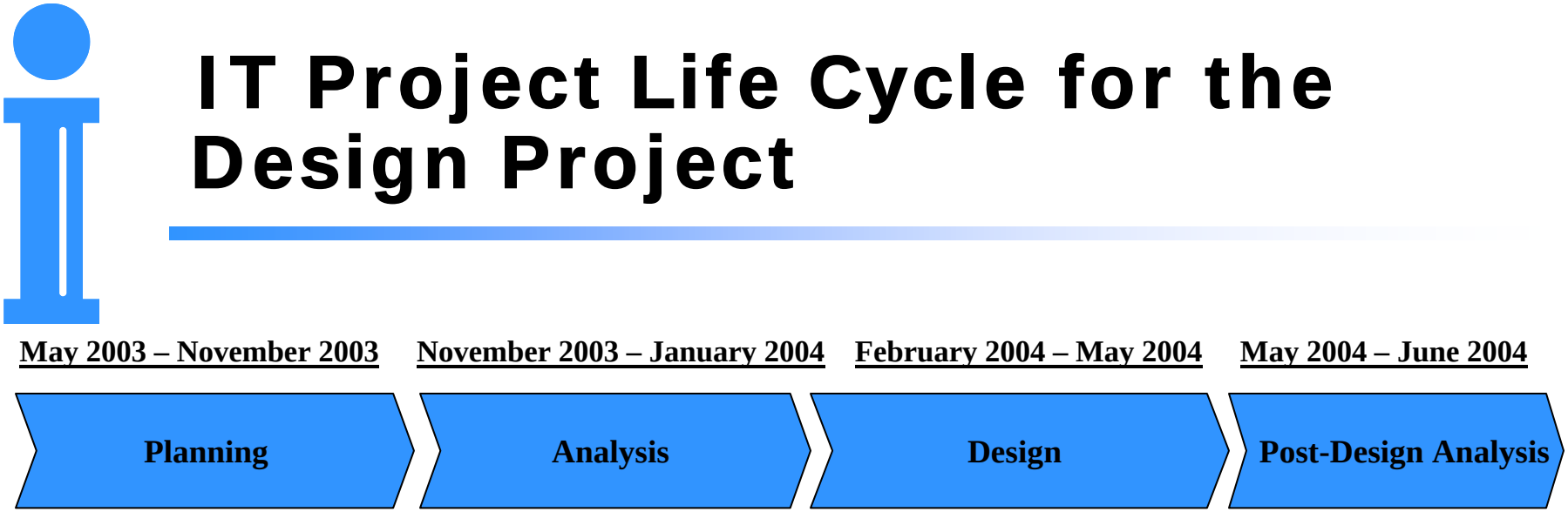
SUBMITTER PACKAGE DETAIL LOGICAL DATA STRUCTURE



Project Plan Highlights

- Kickoff project participant conference calls
- Nine additional project participant conference calls
- Three workgroup face-to-face meetings
- One final project participant face-to-face meeting in Washington, DC (May 17-18, 2004)
- Primary project work completed by the end of May 2004; closeout activities into June 2004

IT Project Life Cycle for the Design Project



Our Framework Includes:

1. Identification of the relevant business processes sets the initial framework for the information system scope
2. The identification of the business processes leads to the identification of the required workflow needed to achieve the goal(s) of the business process
3. Understanding the workflow enables the identification and definition of individual work tasks

Our Framework Includes:

4. Understanding work tasks enables design of the appropriate information system support needed to perform the tasks efficiently
5. Design of the appropriate information system support leads to the identification and definition of the databases required including structure and element content
6. Finally, the data requirements lead to the development of data exchange standards, i.e., PHIN, since the data to be exchanged should be a subset of the required system databases

Questions?

Thank You!

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