The Certification Commission for Healthcare Information Technology (CCHIT)
Update

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Chair, CCHIT

Presented before the
National Committee on Vital and Health Statistics
June 30, 2005
Washington, DC

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Topics to be Covered

- Origin, Mission and Concept
- Organizational Structure
- Scope, Deliverables, and Timeline
- Development Process
- Overview of Work Products and Public Comment Process
- HHS Health IT Strategy and the Future of CCHIT
- Q & A

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Origin, Mission and Concept of CCHIT

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Origins of CCHIT

Goals and Strategies of HHS's Framework for Strategic Action

Goals	Strategies[a]
Goal 1: Inform clinical practice with the use of electronic health records (EHR)	1. Incentivize EHR adoption **2. Reduce risk of EHR investment** 3. Promote EHR diffusion in rural and underserved areas
Goal 2: Interconnect clinicians so that they can exchange health information using advanced and secure electronic communication	**1. Foster regional collaboration** **2. Develop a national health information network** **3. Coordinate federal health information systems**
Goal 3: Personalize care with consumer-based health records and better information for consumers	**1. Encourage use of personal health records** 2. Enhance informed consumer choice 3. Promote use of telehealth systems
Goal 4: Improve public health through advanced biosurveillance methods and streamlined collection of data for quality measurement and research	1. Unify public health surveillance architectures 2. Streamline quality and health status monitoring 3. Accelerate research and dissemination of evidence

Source: HHS.

[a] Phase I strategies are shown in bold type.

Private sector certification of HIT products – a *key action* in the Framework

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Founding of CCHIT

- **Founded by three HIT associations:**
  - American Health Information Management Assoc (AHIMA)
  - Healthcare Information and Management Systems Society (HIMSS)
  - The National Alliance for Health Information Technology (Alliance)
- **Formed panel to nominate first Commissioners**
- **Provided seed funding and resources**
- **First official meeting Sept 14, 2004**

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Broadened Funding Support

- **Unrestricted grants, $110k total, from:**
  - **American Academy of Family Physicians (AAFP)**
  - **American College of Physicians (ACP)**
  - **Hospital Corporation of America**
  - **McKesson**
  - **Sutter Health**
  - **United Health Foundation**
  - **WellPoint Health Networks, Inc.**
- **Grants supporting testing development, $215K total**
  - **California HealthCare Foundation**

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Mission of CCHIT

To accelerate the adoption of robust, interoperable HIT throughout the US healthcare system, by creating an efficient, credible, sustainable mechanism for the certification of HIT products.

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Guiding Principles

- **Timeliness**
  - Need decisive private-sector action now
- **Value**
  - Deliver value for all key stakeholders and the larger healthcare community
  - Process must be efficient and not add net costs
- **Integrity**
  - Operate in credible, objective, transparent manner
  - Certification must be objective, laboratory verified to the greatest extent practical

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Key Points to Clarify

- **Product Certification is different from:**
  - Organizational Accreditation
  - Professional Certification
- **Certification is binary, i.e. "pass/fail"**
  - Not a subjective, comparative rating system
  - Competition and innovation can thrive "above the line"
- **Voluntary process**
  - Initial requirements must be market reality-based
  - A forward-looking requirements roadmap provides the best means to influence market direction

Standards and Certification Create "Tipping Points" for New Technologies

The IBM-standard PC launched the personal computing revolution

The Ethernet networking standard gave PC's connectivity

The Wi-fi standard made it wireless

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How Product Certification Can Accelerate HIT Adoption

- Increase the confidence of providers to invest in and adopt HIT
- Facilitate interoperability of HIT products within the emerging national health information network
- Enhance the availability of HIT adoption incentives from public and private purchasers/payers

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The HIT Adoption Deadlock

Can't offer incentives unless benefits and interoperability of EHRs are assured

Payers/Purchasers

HIT Vendors

Can't bring down costs until provider adoption accelerates

Providers

Hesitant to buy HIT until costs and risks are lower and/or incentives higher

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Breaking the Deadlock

Beneficial effects and interoperability assured, unlocking incentives

Payers/Purchasers

IT Vendors

Growing market attracts investment, lowers costs

Providers

Reduced risk and availability of incentives accelerates adoption

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Key Stakeholder Relationships

Additional Stakeholders: consumers, public health, research, quality org's

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Organization of CCHIT

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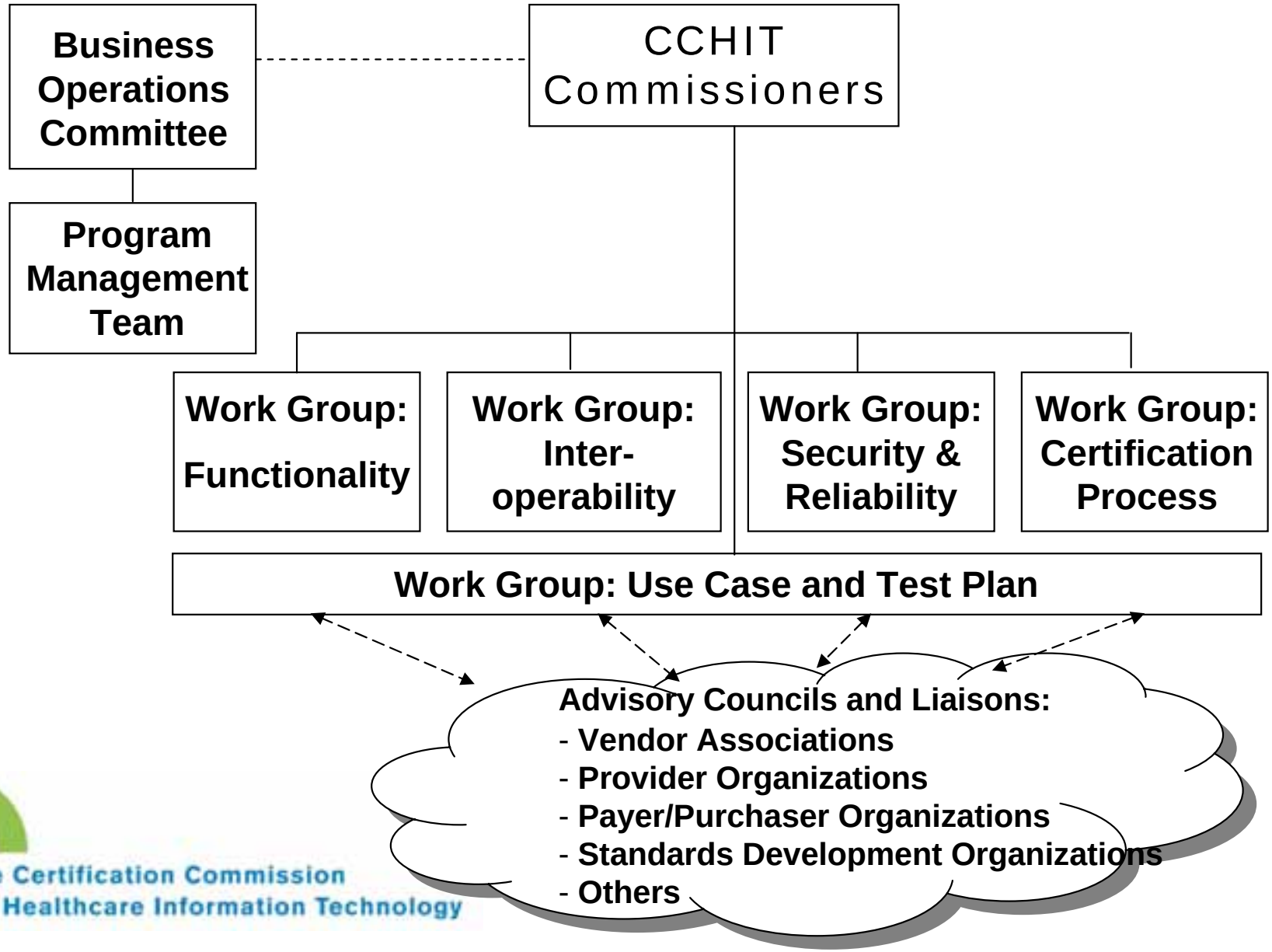
CCHIT Organization



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Stakeholder Balance and Diversity on the Commission and Work Groups

Commission

- **2 – 4 from each key stakeholder group:**
  - Providers
  - Vendors
  - Purchasers/payers/coalitions
- **2 – 4 total drawn from other stakeholders:**
  - Government (ex-officio, nonvoting)
  - Standards development organizations (e.g. HL7)
  - Others, e.g. healthcare consumer advocates, etc.

Work Groups

- **Open Call for Participation**
  - 275 applicants
  - Commissioners ranked by qualifications then adjusted for stakeholder balance
- **Co-Chairs**
  - Two Co-Chairs
  - Must represent two different stakeholders
- **Members**
  - 8 – 10 members
  - Qualified experts
  - Diversity of backgrounds

Scope, Timeline, and Deliverables

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Scope, Deliverables, and Timeline

- **Initial scope**
  - Certify EHR products for physician offices and other ambulatory care settings
- **Deliverables:**
  - Operational capability for certification
  - Roadmap forecasting future certification plans 1-2 years ahead
- **Timeline**
  - Pilot process ready in September 2005

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Certification Roadmap Concept

EHR Product Attributes	Current Year	1 Year Ahead	2 Years Ahead
Functionality	Final 2005 Requirements	Forecast 2006 Requirements	Forecast 2007 Requirements
Interoperability	Final 2005 Requirements	Forecast 2006 Requirements	Forecast 2007 Requirements
Security & Reliability	Final 2005 Requirements	Forecast 2006 Requirements	Forecast 2007 Requirements

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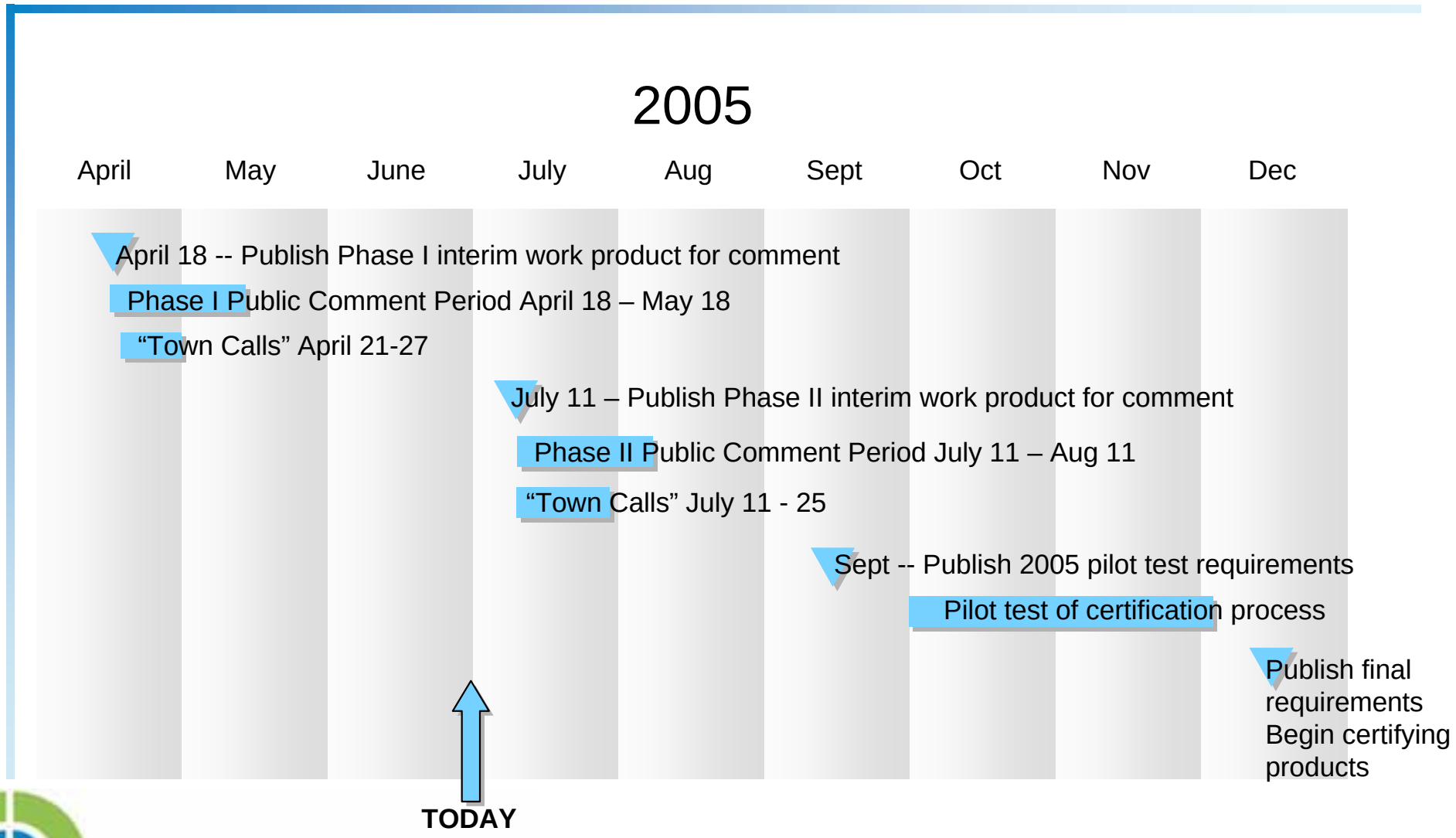
Timeline
(Subject to adjustment)



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Description of Project Phases

- Phase I – Data Gathering
- Phase I Public Comment period
- Phase II – Draft requirements
- Phase II Public Comment period
- Finalize requirements and begin pilot test
- Publish final requirements and roadmap
- Launch product certification

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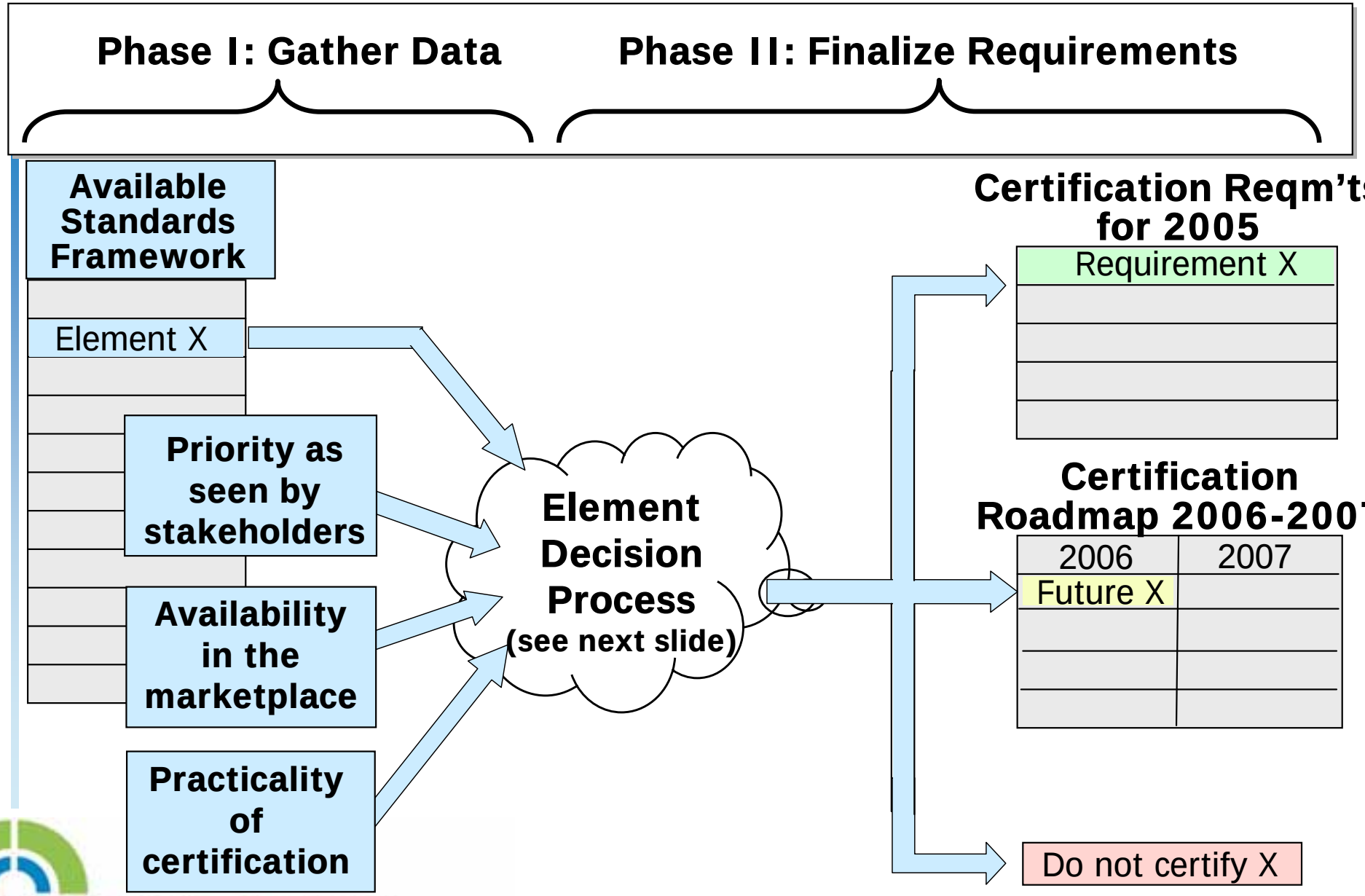
Process for Development of Certification Criteria

Work Group Process



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Element Decision Process

Priority \ Availability	Widely Available	Available in 2006 or 2007	Availability Uncertain
Essential	Certify in 2005	Consider for 2006-07 roadmap	Do not certify
Essential in the Future	Consider for 2006-2007 roadmap	Consider for 2006-2007 roadmap	Do not certify
Optional	Do not certify	Do not certify	Do not certify

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Overview of Work Products and Public Comment Process

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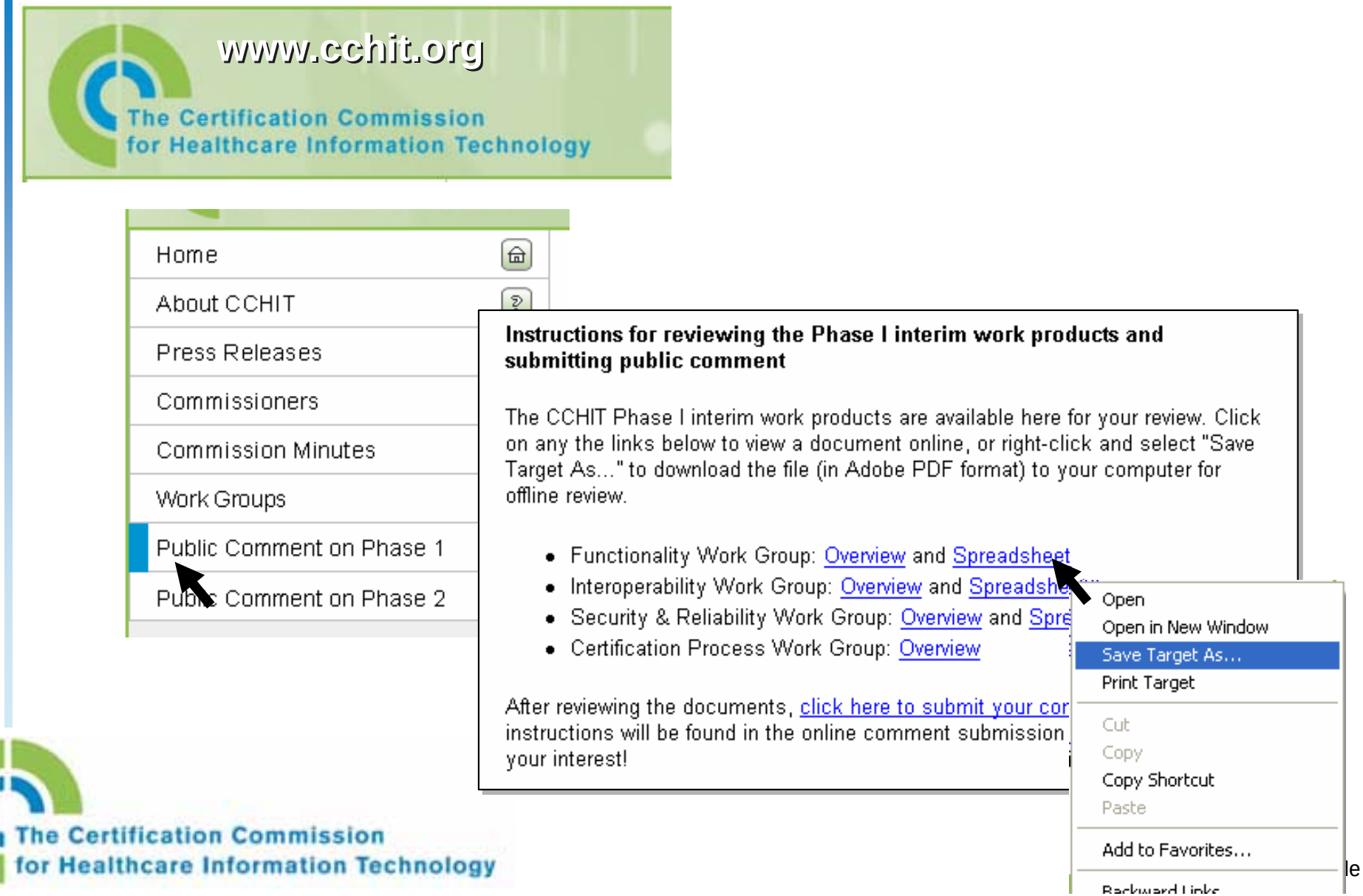
Phase I Work Products on Website (Note: Comment period is now closed)



Functionality Work Group Spreadsheet – Left Portion

CCHIT Functionality Work Group Phase I

Line #	Criterion Name	WG	Criterion Description	Source *(map to Standard source)*	Priorities (L,M,H)			
					Providers	Vendors	Payer/ Purchasers	Other
1	Identify & maintain a patient record	Funct	Key identifying information is stored and linked to the patient record. Both static and dynamic data elements will be maintained. A look up function uses this information to uniquely identify the patient.	DC.1.1.1				
2								
3								
4								
5								
6								
7	Manage patient demographics	Funct	Contact information including addresses & phone numbers, as well as key demographic information such as date of birth, gender, and other information is stored & maintained for reporting purposes and for the provision of care.	DC.1.1.2	These data elements are necessary for determining needed care, contacting the patient.		These individual data elements are needed for tracking disparities in care, trends in disease patterns with regional variation, and help identify potential events related to bioterrorism. Age is needed to track appropriate health services such as	
8								
9								
10								
11								
12	Manage summary lists	Funct	Patient summary lists can be created from patient specific data and displayed and maintained in a summary format. The functions below are important,	DC.1.1.3	This is important to providers for quickly assessing the			These are important to patients who
13								

MORE

Line Numbers

Functions from HL7 EHR TC DSTU (Subset)

Evidence on Priorities

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Functionality Work Group Spreadsheet – Right Portion

MORE

Availability			Test Method	Test Specification	Recommendation			
2005	2006	2007			Certify in 2005	Roadmap for 2006	Roadmap for 2007	
H			1. The system **SHALL** create a single patient record for each patient.					
H			2. The system **SHALL** associate (store/link) key identifier information with each patient record.					
H			3. The system **SHALL** store multiple identifiers for each patient record.					
H			4. Using the key identifying information, the system **SHALL** identify (look up) the unique patient record.					
H			5. The system **SHALL** maintain and make available dynamic data elements for each patient record.					
H			6. The data in the patient record and the integrity or the record itself **SHALL** be maintained until specifically deleted based on local policies, procedures and/or applicable laws and regulations.					
H			1. The system **SHALL** capture and maintain demographic information as part of the patient record.					
H			2. The system **SHALL** provide ability to report demographic information.					
M			3. The system **SHALL** keep track of demographic information over time.					
H			4. The system **SHALL** allow a user to modify demographic information about the patient.					

Evidence on Availability

Conformance Criteria and Test Specifications

To be developed (Phase II): 2005 Criteria and 2006-07 Roadmap

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Interoperability Work Group Spreadsheet

			CCHIT Interoperability Workgroup Phase I: Collection of Data and Assessment of the Industry							
Line Num.	Highlighted cases	ID	Use Case Component	Description	Priorities: Providers	Priorities: Payers/ Purch-asers	Discussion / Barriers to Market Availability	Source Standard or Vocabulary	Implementaion Guide	Source Available Today?
1	*Laboratory and Imaging*									
2		L.1	Receive results	Results using common vocabulary with inbound interface optionality removed	H	M	(1) Interface optionality; (2) lack of standard result and result values vocabularies; (3) non-standard handling of microbiology; (4) Coding standards (once defined) must be kept current. Process must be efficient and fast to keep up with the addition of new tests; (5) Need to provide discrete data and laboratory specific reports. This is especially true for anatomical pathology and esoteric reporting. (6) Myriad of communication architectures increases costs to support send and receipt of results. (7) What is business model to support real-time results feeds? Who will pay? (8) Potential for innovation (technological and clinical) to be throttled by standards bodies.			
3								HL7 v2.4		X
4								HL7 v3		
5								LOINC result naming		X
6							Result values naming	SNOMED		X
7									CCDP Implementation Guide - Batch	X

Line Numbers

Interoperability Use Cases – Priority cases highlighted

Evidence on standards, vocabularies, barriers, and availability

To be developed (Phase II): 2005 criteria and 2006-07 roadmap

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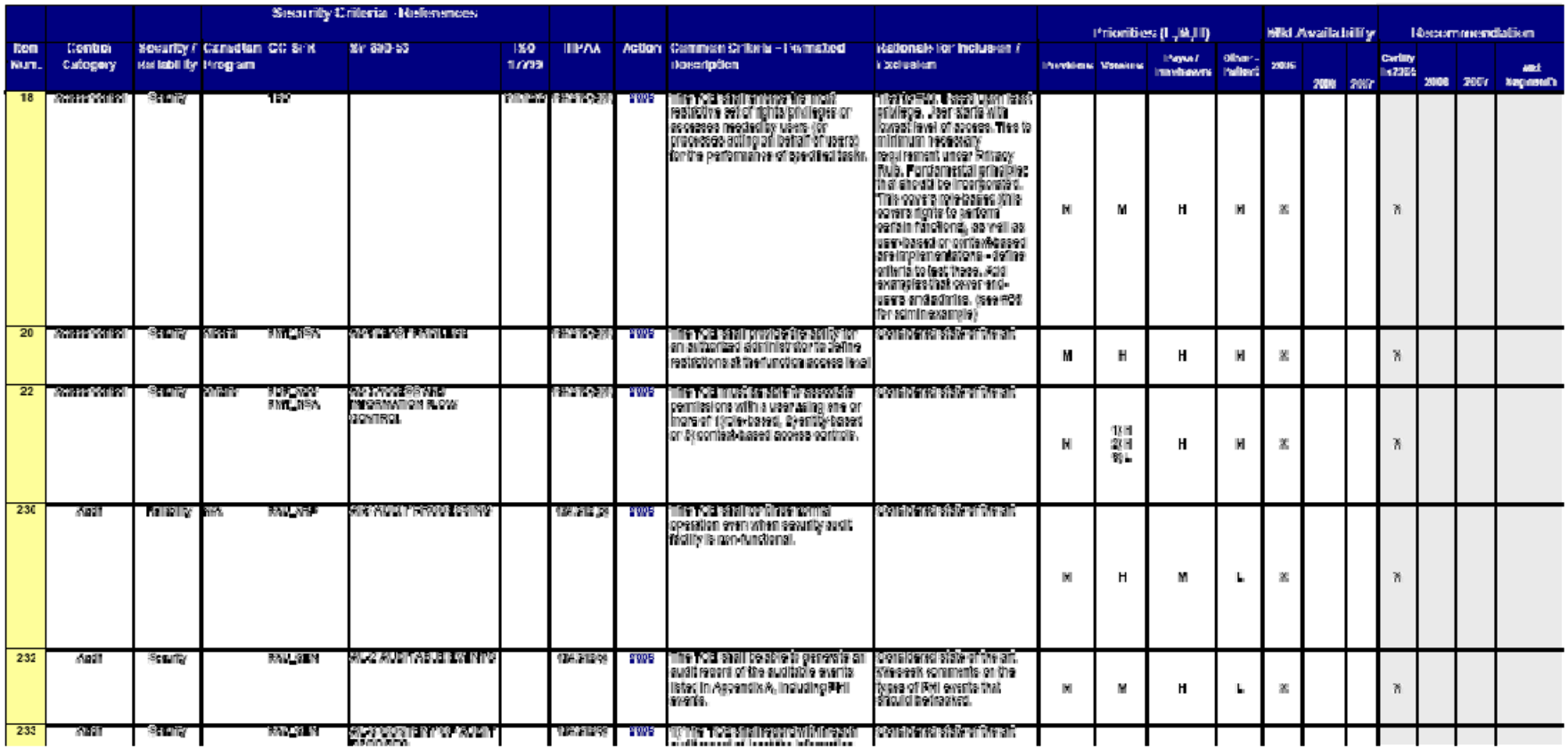
Security & Reliability Work Group Spreadsheet



Line Numbers

Security Criteria with references and rationale for inclusion/exclusion

Priorities and market availability

Preliminary recommendations (to be refined in Phase II)

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Certification Process Work Group Overview Document

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Certification Process Work Group
Phase I Deliverable for Public Comment

I. Introduction

The Certification Process Work Group (CPWG) is pleased to present its Phase I report on its progress towards identifying the essential elements of a certification process for ambulatory electronic health records. The CPWG is actively seeking feedback on this Phase I deliverable in order to develop a consensus-based model that will serve the needs of the various stakeholders within the process. The goal of Phase I was to develop an assessment of current and potential testing methodologies and then provide a summary for public comment.

Phase I included the following deliverables:

- Research and examine a variety of current certification testing processes that had similar objectives to those of the CCHIT.
- Develop a summary of possible testing approaches
- Research capabilities of current software testing laboratories
- Construct a framework for an idealized certification process for electronic health records.

Phase II will commence once the initial public comment period has been completed. Phase II deliverables include the following:

- Details regarding the specific testing processes for certifying the individual criteria developed by the other Work Groups
- Specific cost estimates will be developed once the fundamental decisions regarding the methods, location and sponsoring organization(s) are reached.

There are two levels to defining a certification process for electronic health records:

- The first level is outlining the macro level process. This includes everything from the application process to the

Line numbers – refer to these in the comment submission form.

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Phase I
Public Comment Period: Preliminary Results

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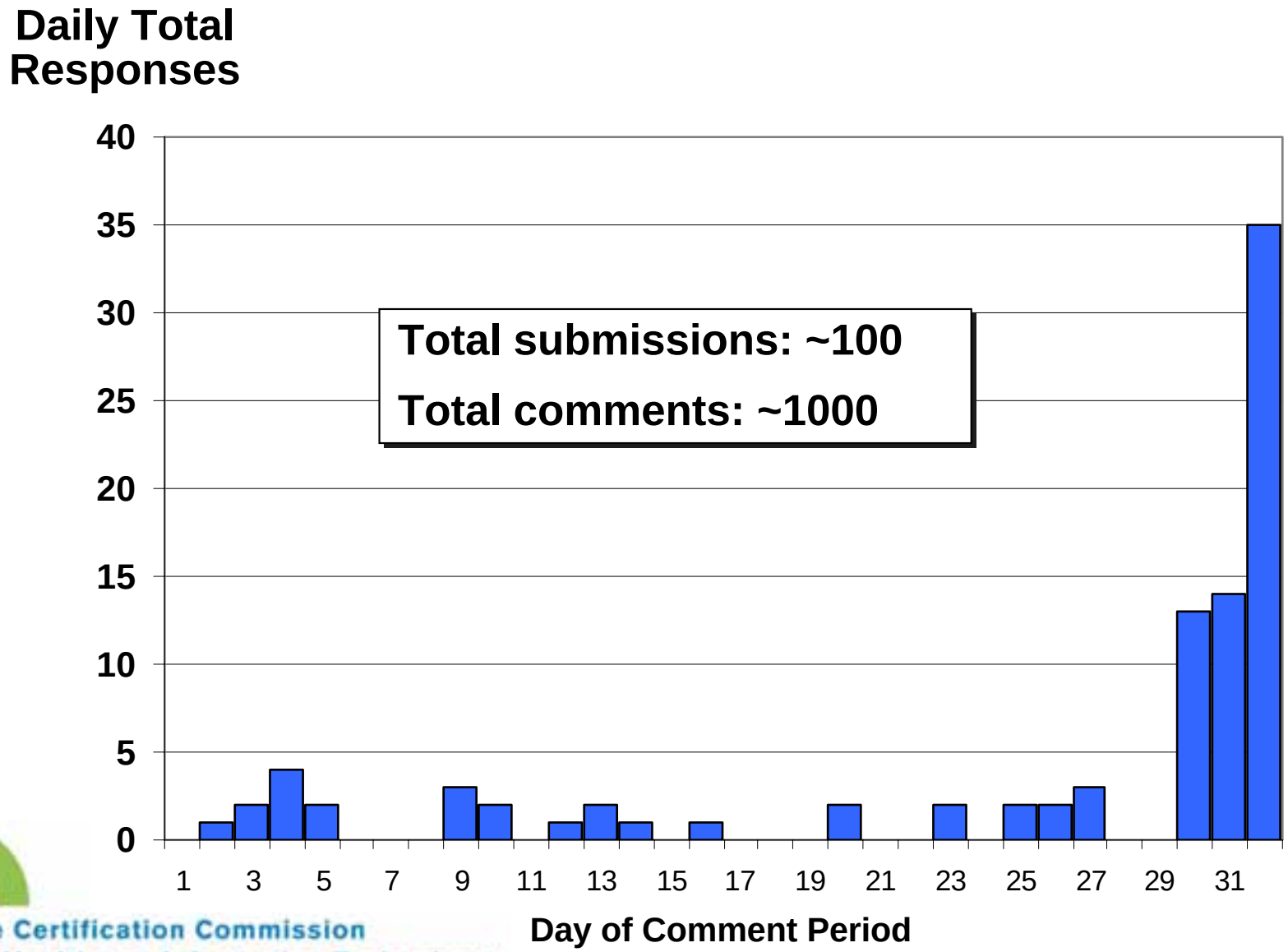
Phase I Public Comment: Response Volume and Timing



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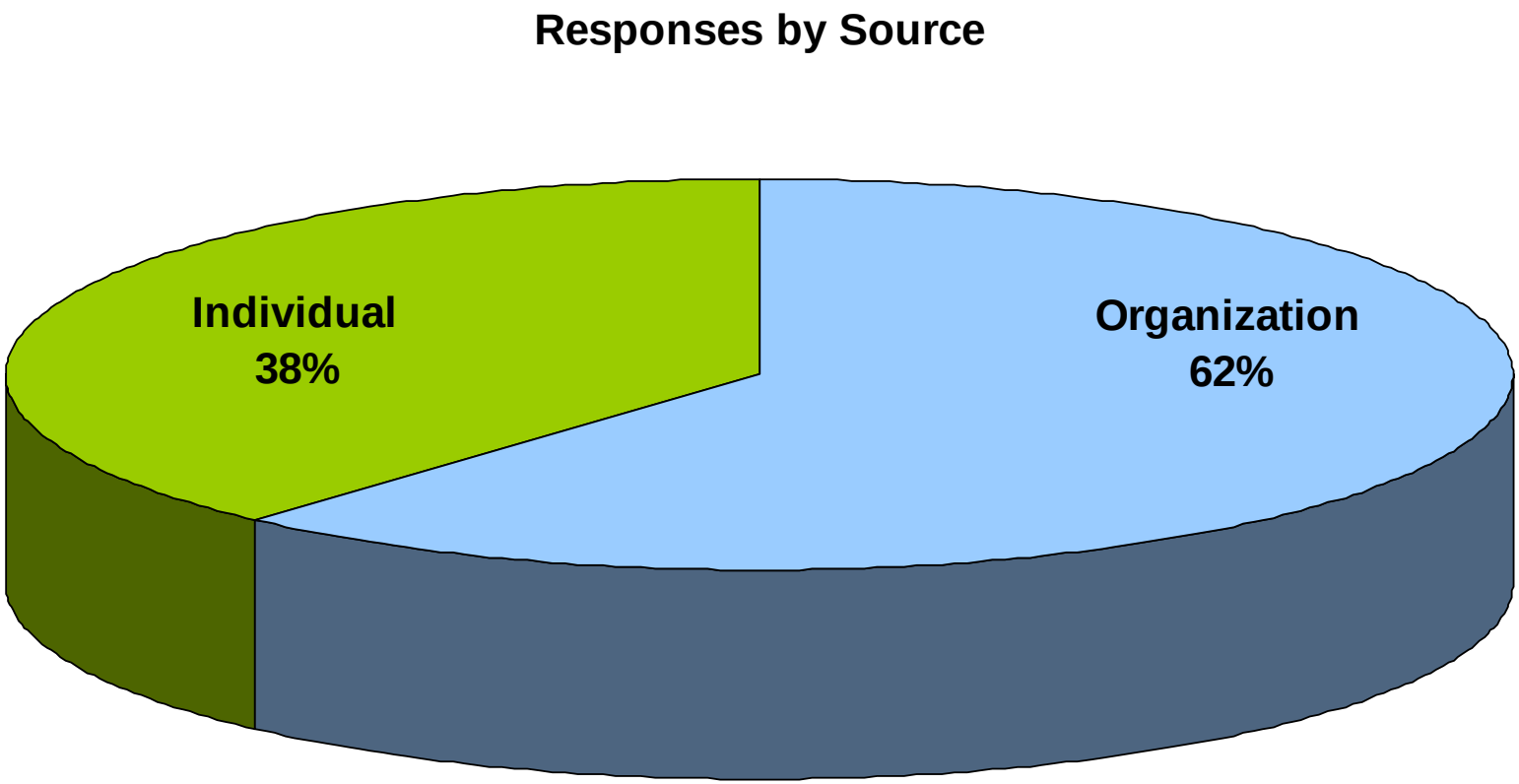
Phase I Public Comment: Responses by Source



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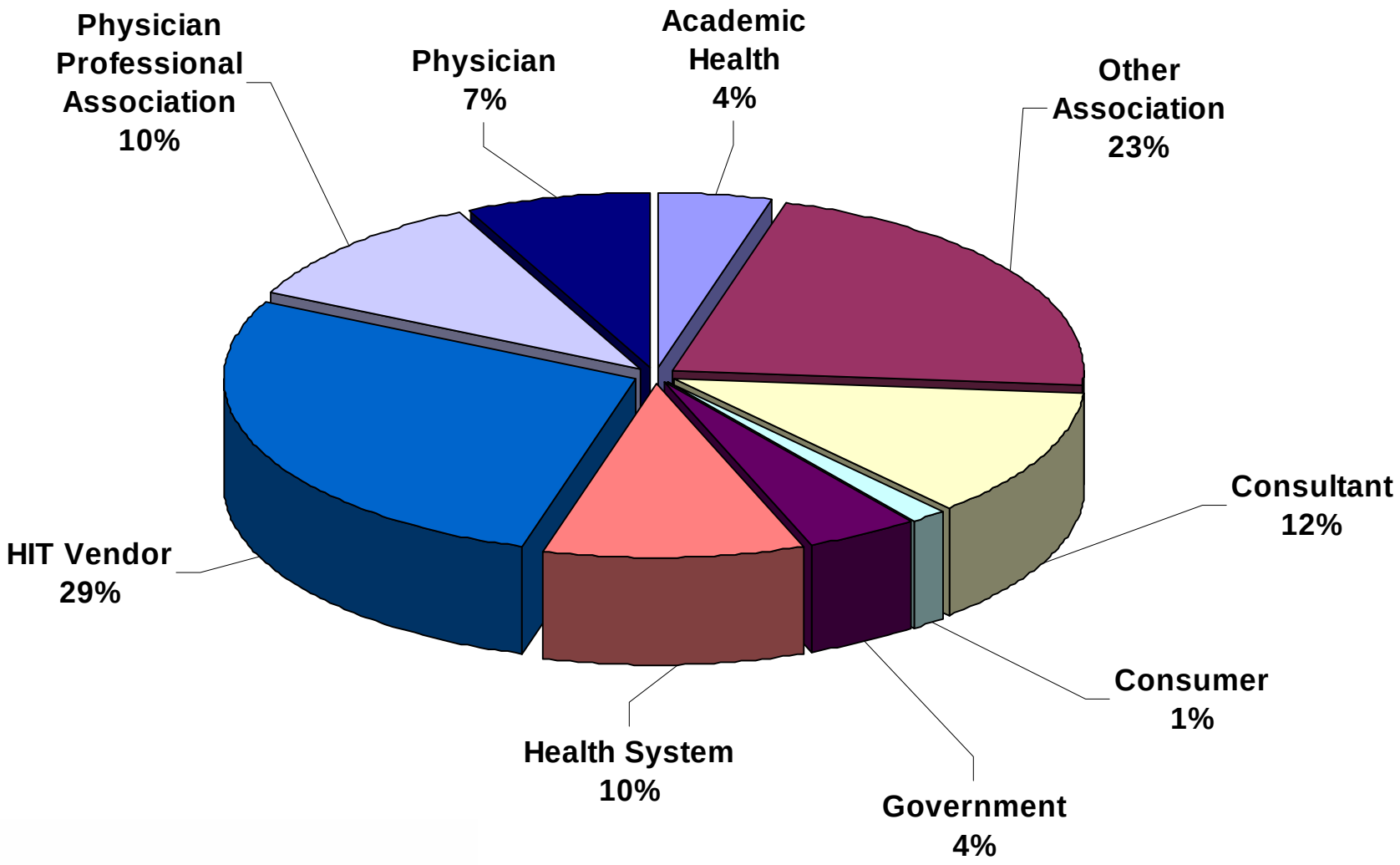
Phase I Public Comment: Responses by Category



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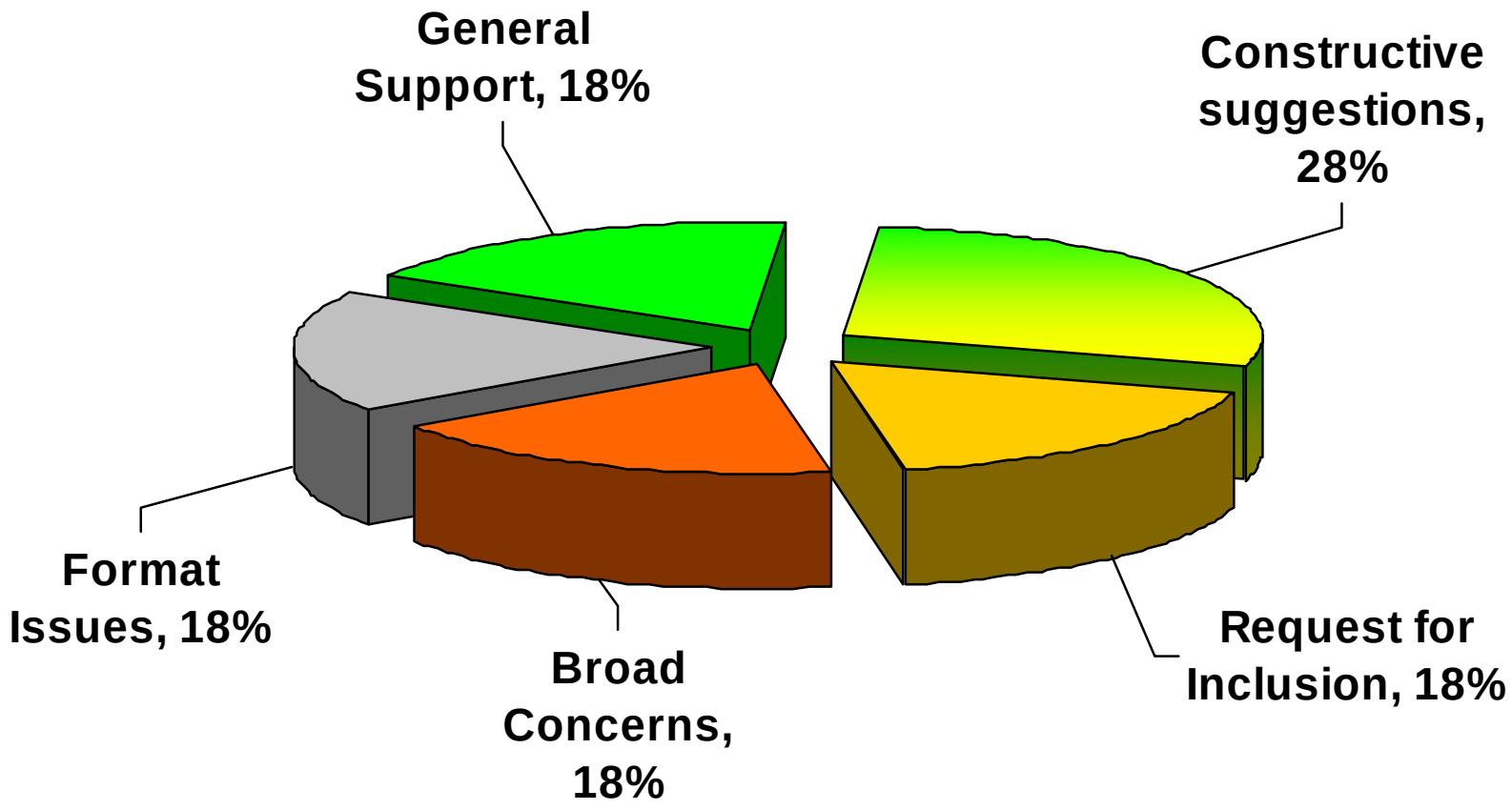
Phase I Public Comment: General Responses for Commission (does not include comments for WGs)

TOTAL: 28



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Phase II
Work Products:
Preview of Changes

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Phase II Work Products Will Be Available on Website July 11

www.cchit.org

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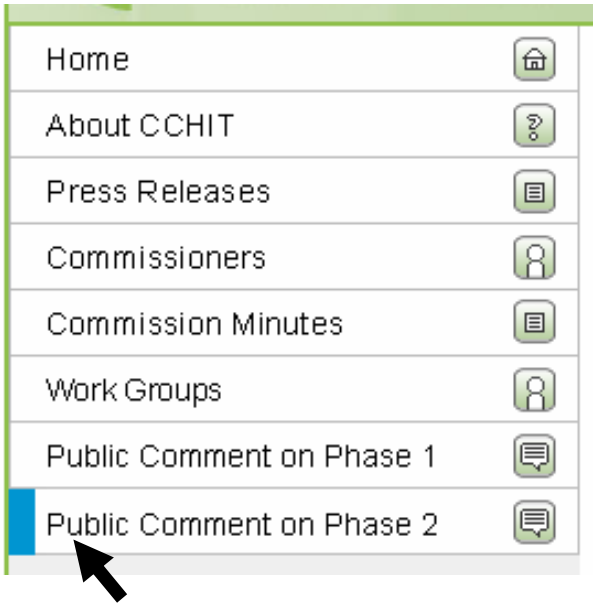
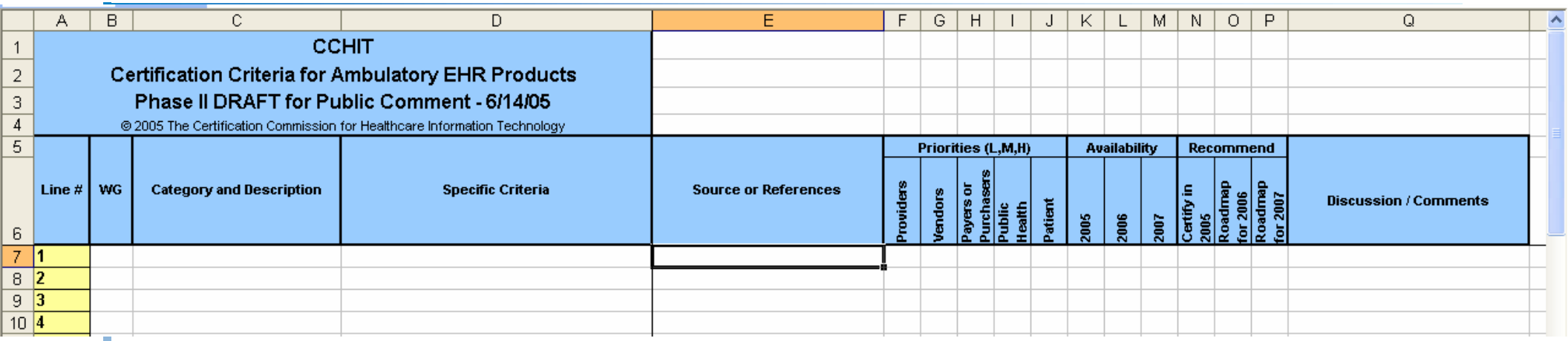


New Common Format



	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q
1	CCHIT																
2	Certification Criteria for Ambulatory EHR Products																
3	Phase II DRAFT for Public Comment - 6/14/05																
4	© 2005 The Certification Commission for Healthcare Information Technology																
5						Priorities (L,M,H)					Availability			Recommend			
6	Line #	WG	Category and Description	Specific Criteria	Source or References	Providers	Vendors	Payers or Purchasers	Public Health	Patient	2005	2006	2007	Certify in 2005	Roadmap for 2006	Roadmap for 2007	Discussion / Comments
7	1																
8	2																
9	3																
10	4																

Criteria from Functionality, Interoperability, Security & Reliability Work Groups now "harmonized" in a common format

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Crosswalk: Functionality

Line #	WG	Category and Description	Specific Criteria	Source or References	Providers	Vendors	Payers or Purchasers	Public Health	Patient	2005	2006	2007	Certify in 2005	Roadmap for 2006	Roadmap for 2007	Discussion / Comments
1	F	**Identify & maintain a patient record:** Key identifying information is stored and linked to the patient record. Both static and dynamic data elements will be maintained. A look up function uses this information to uniquely identify the patient	1. The system shall create a single patient record for each patient.	DC.1.1.1						H						
2			2. The system shall associate (store/link) key identifier information with each patient record.	DC.1.1.1						H						
3			3. The system shall store multiple identifiers for each patient record.	DC.1.1.1						H						
4			4. Using the key identifying information, the system shall identify (look up) the unique patient record.	DC.1.1.1						H						
5			5. The system shall maintain and make available dynamic data elements for each patient record.	DC.1.1.1						H						
6			6. The data in the patient record and the integrity or the record itself shall be maintained until specifically deleted based on local policies, procedures and/or applicable laws and regulations.	DC.1.1.1						H						
7	F	**Manage patient demographics:** Contact information including addresses & phone numbers, as well as key demographic information such as date of birth, gender, and other information is stored & maintained for reporting purposes and for the provision of care	1. The system shall capture and maintain demographic information as part of the patient record.	DC.1.1.2	These data elements are necessary for determ		These individual data elements are needed for tracking disparities in care, trends in disea			H						
8			2. The system shall provide ability to report demographic information.	DC.1.1.2						H						
9			3. The system shall keep track of demographic information over time.	DC.1.1.2						M						
10			4. The system shall allow a user to modify demographic information about the patient.	DC.1.1.2						H						
11			5. Demographic information shall be stored in the patient medical in separate data fields, such that data extraction tools can subsequently be used to retrieve this data.	DC.1.1.2						H						
12	F	**Manage summary lists:** Patient summary lists can be created from patient	1. The system shall create and maintain a summary list for each patient.	DC.1.1.3	This is imp				These are important	H						
13			2. The system shall be capable of including	DC.1.1.3						M						

CCHIT Functionality Work Group Phase I

Line #	Criterion Name	WG	Criterion Description	Source *(map to Standard source)*	Priorities (L,M,H) Providers	Vendors	Payer/ Purchasers	Other	Availability 2005	2006	2007	Test Method	Test Specification	Recommendation Certify in 2005	Roadmap for 2006	Roadmap for 2007	Possible mkt segment-	Discussion / Rationale
1	Identify & maintain a patient record	Funct	Key identifying information is stored and linked to the patient record. Both static and dynamic data elements will be maintained. A look up function uses this information to uniquely identify the patient.	DC.1.1.1					H			1. The system **SHALL** create a single patient record for each						
2									H			2. The system **SHALL** associate (store/link) key identifier						
3									H			3. The system **SHALL** store multiple identifiers for each patient						
4									H			4. Using the key identifying information, the system **SHALL**						
5									H			5. The system **SHALL** maintain and make available dynamic data						

Crosswalk: Interoperability

Line #	WG	Category and Description	Specific Criteria	Source or References	Priorities (L,M,H)					Availability			Recommend			Discussion / Comments
					Providers	Vendors	Payers or Purchasers	Public Health	Patient	2005	2006	2007	Certify in 2005	Roadmap for 2006	Roadmap for 2007	
1	I	Laboratory and Imaging	**Receive results** using common vocabulary with inbound interface optionality removed	HL7 V2.x available now; HL7 V3 in dev; LOINC for results naming (etc)	H		M									Discuss obstacles and solutions here!
2			**Send orders to lab systems**: Complete order must be defined (mimimum dataset). There is no good definition for a minimum data set for an order message. Laboratory costs are higher if electronic orders are incomplete	HL7 V2.x available now; HL7 V3 in dev; LOINC for results naming (etc)	H		H									
3	I		**Receive PACS images, photos and EKG images**													

Line Num.	Highlighted cases	ID	Use Case Component	Description	Priorities: Providers	Priorities: Payers/ Purch-asers	Discussion / Barriers to Market Availability	Source Standard or Vocabulary	Implementaion Guide	Source Available Today?
1			***Laboratory and Imaging***							
2		**L.1**	**Receive results**	Results using common vocabulary with inbound interface optionality removed	H	M	(1) Interface optionality; (2) lack of standard result and result values vocabularies; (3) non-standard handling of microbiology; (4) Coding standards (once defined) must be kept current. Process must be efficient and fast to keep up with the addition of new tests; (5) Need to provide discrete data and laboratory specific reports. This is especially true for anatomical pathology and esoteric reporting. (6) Myriad of communication architectures increases costs to support send and receipt of results. (7) What is business model to support real-time results feeds? Who will pay? (8) Potential for innovation (technological and clinical) to be throttled by standards bodies.			
3								HL7 v2.4		X
4								HL7 v3		
5								LOINC result naming		X
6							Result values naming	SNOMED		X
7									CCDP Implementation Guide - Batch	X
8							Timeline of CCDP workgroup is the throttle: they have done the batch model to this point but not the real-time model.		CCDP Implementation Guide - Real-time	
9									CDC Real-time implementation guide	X
10		**L.2**	**Send orders to lab systems**		H	H	(1) Complete order must be defined (mimimum dataset). There is no good definition for a minimum data set for an order message. Laboratory costs are higher if electronic orders are incomplete.			
11								HL7 v2.3		X

Crosswalk: Security and Reliability

Line #	WG	Category and Description	Specific Criteria	Source or References	Priorities (L,M,H)					Availability			Recommend			Discussion / Comments
					Providers	Vendors	Payers or Purchasers	Public Health	Patient	2005	2006	2007	Certify in 2005	Roadmap for 2006	Roadmap for 2007	
1	SR	**Security**: Access Control	The system shall enforce the most restrictive set of rights/privileges or accesses needed by users (or processes acting on behalf of users) for the performance of specified tasks.	ISO 17799: 9.1.1.2.b; HIPAA: 164.312(a)(1)	H	M	H		H	X			X			Tied to #20. Based upon least privilege. User starts with lowest level of access. Ties to minimum necessary requirement under Privacy Rule. Fundamental principles that should be incorporated. This covers role-based (this covers rights to perform certain functions) as well as user-based or context-based are implementations - define criteria to test these. Add examples that cover end-users and admins. (see #66 for admin example)
2			The system shall provide the ability for an authorized administrator to define restrictions at the function access level	Canadian: Alberta; CC SFR: FMT_MSA; SP800-53: AC-5 LEAST PRIVILEGE; HIPAA: 164.312(a)(1)	M	H	H		H	X			X			Considered state of the art
3			The system must be able to associate permissions with a user using one or more of 1)role-based, 2) entity-based or 3) context-based access controls.													
4	SR	**Security**: Audit	The system shall continue normal operation even when security audit facility is non-functional.													
5																

Item Num.	Control Category	Security / Reliability	Canadian Program	CC SFR	SP 800-53	ISO 17799	HIPAA	Action	Common Criteria - Formatted Description	Rationale for Inclusion / Exclusion	Priorities (L,M,H)				Mkt Availability			Recommendation			
											Providers	Vendors	Payers / Purchasers	Other - Patient	2005	2006	2007	Certify in 2005	2006	2007	Mkt Segment %
18	Access Control	Security		TBD		9.1.1.2.b	164.312(a)(1)	2005	The TOE shall enforce the most restrictive set of rights/privileges or accesses needed by users (or processes acting on behalf of users) for the performance of specified tasks.	Tied to #20. Based upon least privilege. User starts with lowest level of access. Ties to minimum necessary requirement under Privacy Rule. Fundamental principles that should be incorporated. This covers role-based (this covers rights to perform certain functions), as well as user-based or context-based are implementations - define criteria to test these. Add examples that cover end-users and admins. (see #66 for admin example)	H	M	H	H	X			X			
20	Access Control	Security	Alberta	FMT_MSA	AC-5 LEAST PRIVILEGE		164.312(a)(1)	2005	The TOE shall provide the ability for an authorized administrator to define restrictions at the function	Considered state of the art	M	H	H	H	X			X			
22	Access Control	Security	Ontario	FDP_ACC FMT_MSA	AC-3 ACCESS AND		164.312(a)(1)	2005	The TOE must be able to associate permissions with a	Considered state of the art											

First Draft of “Use Cases”

- **Use cases: realistic clinical scenarios for test purposes**
- **Use cases should demonstrate product fulfillment of functionality, interoperability, and security criteria**
- **Common use cases will help unify and coordinate efforts in the new HHS health IT strategy**

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HHS Health IT Strategy and the Future of CCHIT

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New HHS Health IT Initiatives Announced June 6-7, 2005

- **American Health Information Community**
  - Chaired by HHS Secretary Mike Leavitt
  - Five specific tasks requiring recommendations
- **Four RFP's released June 7**
  - Standards harmonization process
  - Compliance certification and inspection process*
  - Prototypes for a National Health Information Network
  - Privacy and security solutions for interoperable health information exchange

***CCHIT is responding to this RFP**

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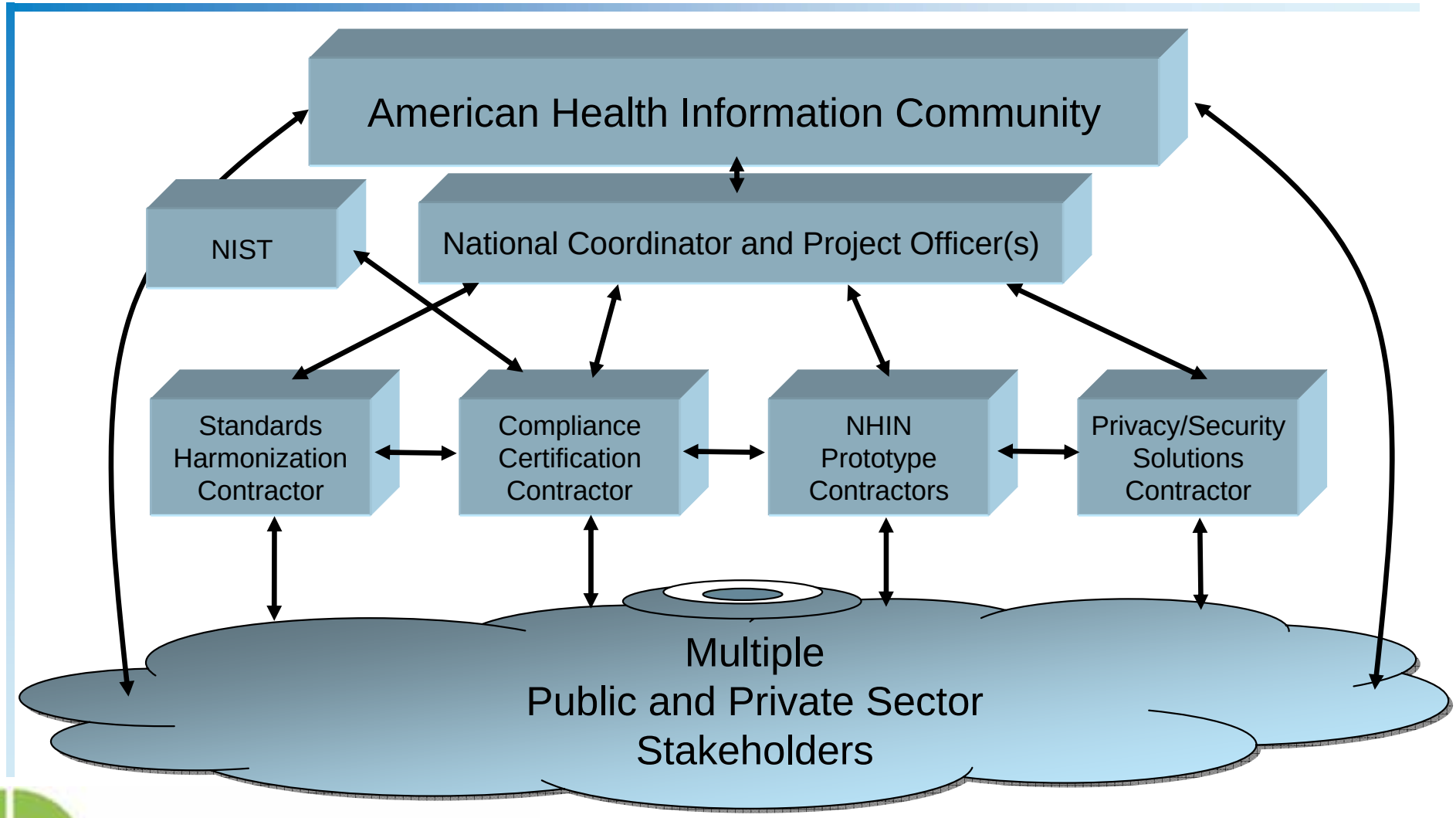
Collaborative Relationships



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Thank You!
Q and A

For more information, please visit the website:

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