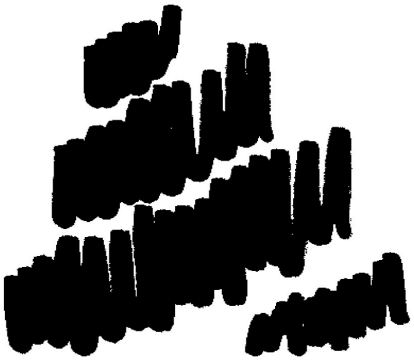
CONNECTIVITY INDUSTRY CONSORTIUM

CIC

ORGANIZATION PLAN



Connectivity

This document contains the Organization Plan of the Point of Care Connectivity Industry Consortium (CIC). It reflects the input gathered at the first Consortium meeting on October 20, 1999 and subsequent discussions. Appendix I contains the Consortium Bylaws. Appendix II contains a summary of the Consortium's membership categories, obligations and privileges. Appendix III contains a detailed projection of the 12-15 month CIC budget.

TABLE OF CONTENTS

1 NAME

The name of the organization shall be the Connectivity Industry Consortium. It may be referred to as the Consortium and the CIC hereafter.

2 BACKGROUND

At the request of the Point of Care (POC) division of the American Association of Clinical Chemistry (AACC), Agilent Technologies organized an open meeting attended by the POC/IVD industry, LIS/HIS suppliers, health care providers and consultants. The meeting was held in Redwood City, California, October 20 1999, and attended by 122 individuals, representing 63 organizations.

The intent of this meeting was to assemble an open, industry-wide forum to address problems and outline practical solutions for POC connectivity. At this meeting, the objectives, organizational structure, and timeline for a new Connectivity Industry Consortium were presented.

Over the next 12-15 months, the CIC will prepare a base-level standard for POC connectivity and transfer the results to an established industry standards-setting organization. The goal of this standard is to provide a technical solution for POC connectivity that meets worldwide user community requirements, while enabling vendors to build differentiating features, functions, and applications. The Consortium will utilize existing standards and commercial implementations where possible. Both a multi-vendor connectivity demonstration and preliminary pilot study results are planned for late fall 2000.

The Consortium's legal and organizational structure will be established during December 1999 and January 2000. By the end of 1999, the Consortium's founding member organizations will have ratified the Consortium Plan and Bylaws, and signed a binding Letter of Agreement to participate in the Consortium. In early January, the Consortium's Board of Directors and Executive staff will be elected, the Consortium will be incorporated as a non-profit entity, and dues will be collected from the member organizations. The CIC will be fully staffed and operational by the end of January 2000.

3 PURPOSE, OBJECTIVES AND APPROACH

3.1 PURPOSE

The mission of the proposed Connectivity Industry Consortium is to prepare a base-level standard for connectivity in 12-15 months, and donate the resulting standard for maintenance and further refinement to an existing, established industry standards-setting organization selected by the consortium membership (e.g. IEEE, HL7, ASTM). It is the intent of the Consortium to provide standards that, through their clinical, technical and economic benefits, will be requested by health care providers and widely implemented by vendors.

3.2 OBJECTIVES

1) Draft and demonstrate a baseline bi-directional POC connectivity standard in 12-15 months
    - Adhere to the 80/20 rule to achieve success in a commercially viable time frame to insure that standards keep pace with advances in technology.
2) Provide a technical solution that…
    - Addresses the key objectives of the POC user community
    - Allows POC suppliers to build additional differentiating features and functions to offer to their customers.
3) Utilize, where possible, proven existing standards and commercial implementations.
4) Transfer the standard to one or more selected standards-setting organizations when these objectives have been fulfilled.

3.3 APPROACH

3.3.1 METHODOLOGY

The Consortium will develop and publish connectivity standards based upon the experience of existing methods and systems. The Consortium will not establish standards that favor the proprietary characteristics or interests of specific systems or companies.

3.3.2 OWNERSHIP

The information content of Consortium standards shall be in the public domain but the connectivity standards documents themselves or other productions thereof will be the intellectual property of the Consortium. The Consortium will expressly reserve the sole rights to publish and sell the documentation of its standards, and will exercise all applicable copyrights to these materials. These rights will be transferred along with the standards to another standards organization(s) when the Consortium has fulfilled its objectives.

3.3.3 OPERATIONS

The Consortium will operate with funds derived from membership dues. The Consortium itself will be a non-profit enterprise and no part of the Consortium income or earnings will accrue to the benefit of any officer, chair, participant, or contributor.

4 SCOPE OF WORK

The Consortium will address, at minimum, such fundamental technical areas as:

- Device interface
- EDI interface
- Security
- Information model
- QA/QC reporting.

The Consortium will concentrate on the development of a basic, commercially implementable standard capable of solving the core problems inherent in two-way data transport and integration. The Consortium will leave further enhancement, refinement, and maintenance to the selected standards-setting organization to which the standard is to be transferred.

5 METHODOLOGY

The following sections outline the Consortium's projected budget, the available membership categories, and members' funding obligations and voting privileges.

5.1 BUDGET

The projected budget for the 12-15 month CIC lifetime totals $570,600, as summarized in Table 1. This budget was developed based on the experience gained from similar projects (e.g. the Andover Working Group and the NCCLS Area Committee on Automation), Agilent Technologies' experience with the CIC to date, and input from CIC member organizations. Appendix III contains the detailed breakdown of the budget.

As specified in Appendix I, Section 4.1, any funds remaining upon dissolution of CIC will be refunded to the membership, based on the initial funding contribution.

Table 1: CIC Budget Summary

DIRECT COSTS	
Consortium General Meetings (2)	$60,000
Technical Committee Meetings	$134,500
Website, Publications, Development Tools	$60,000
OVERHEAD EXPENSES	
Communications	$48,000
Pilot Expenses (2 pilots)	$80,000
Incorporation Expenses, Accounting	$12,000
Temporary, Administrative Assistants	$70,000
General Printing and Supplies	$11,000
Subtotal	$475,500
20% overrun contingency	$95,100
Total	**$570,600**

5.2 MEMBERSHIP CATEGORIES, OBLIGATIONS AND PRIVILEGES

All classes of vendor participants have voting rights, which are proportional to the funding obligations. Provider participants are not required to provide funding and have voting rights only in the Provider Review Committee. Affiliate and Evaluating Members have no voting rights.

Table 2: Membership Categories, Obligations and Privileges

Membership Category[1]	Examples	Obligations					Privileges				
		Financial Support	Skilled Resources	Pilot Trials	Put Standard in Product	Put Standard in Orders	Board of Directors Eligibility	TCC[2] Vote	PRC[3] Vote	CIC Vote	Early Access to Information
Core Vendor	Major Suppliers	$50,000	Yes	Negotiable	Preferred Option	N/A	Yes	Yes	N/A	Yes	Yes
Core Provider	Health Systems Major Hospitals	0$	Yes	Negotiable	N/A	Preferred Option	Yes	If appointed	Yes	No	Yes
Supporting Level A	Medium Size Companies	$10,000	Optional	Optional	Preferred Option	N/A	No	If appointed	N/A	Yes	Yes
Level B	Small[4] Companies	$5,000	Optional	Optional	Preferred Option	N/A	No	If appointed	N/A	Yes	Yes
Evaluating Member	Consultants, Organizations w/o commercial POC presence	$5,000	Optional	No	No	No	No	No	No	No	Yes
Affiliates[5]	Standards Organization	$0	Optional	No	No	No	No	No	No	No	Yes

[1] Corporations only, since the CIC is a Consortium
[2] Technical Coordinating Committee
[3] Provider Review Committee
[4] Companies with 1998 revenues under $3 million
[5] Open meetings; anyone may attend (no obligations, no privileges)

5.3 MEMBERSHIP FEES AND VOTING RIGHTS

With one exception, each $5,000 of funding obligation purchases one vote (with a maximum of 10 votes possible for any one organization). The exception to this rule is for Evaluating Members. These members are organizations, such as consulting firms, which do not have commercial products in the POC market, who want to have the early access to Consortium information afforded all members. Evaluating Members pay a $5,000 membership fee, but do not receive any voting privileges.

Core Vendors will contribute $50,000 and be eligible for 10 votes. Supporting members will contribute either $10,000 (Level A) or $5,000, (Level B) depending on the total revenues of the member's organization. Supporting members with 1998 annual revenues above $3 million will provide Level A support while supporting members with 1998 annual revenues below $3 million will be asked for Level B support. Affiliates pay no fee and receive no voting privileges.

Core Providers are not obligated to contribute a fee, and are not eligible for any votes in general CIC ballots. However, they are expected to contribute technical and clinical expertise instead of funding, and as members of the Provider Review Committee are entitled to vote on proposed standards in that Committee.

Table 3: Membership Fees and Voting

TYPE	FEE	VOTES
Core Vendor	$50K	10
Core Provider	$0	-
Supporting (A)	$10K	2
Supporting (B)	$5K	1
Evaluating	$5K	-
Affiliate	$0	-

The following table outlines the distribution of fees and votes for a 50-member scenario.

Table 4: Fees and Votes, 50-Member Scenario

MEMBER TYPE	NUMBER	FEES ($K)		VOTES		
		Fee	Total	Votes (each)	Total	Relative
Core Vendor	10	$50	$500	10	100	71%
Core Provider	5	$0	$0	-	-	0%
Supporting Member (A)	15	$10	$150	2	30	21%
Supporting Member (B)	10	$5	$50	1	10	8%
Evaluating Member	5	$5	$25	-	-	0%
Affiliate Member	5	$0	$0	-	-	0%
Total	**50**		**$725**		**140**	

5.4 CONSORTIUM ORGANIZATION

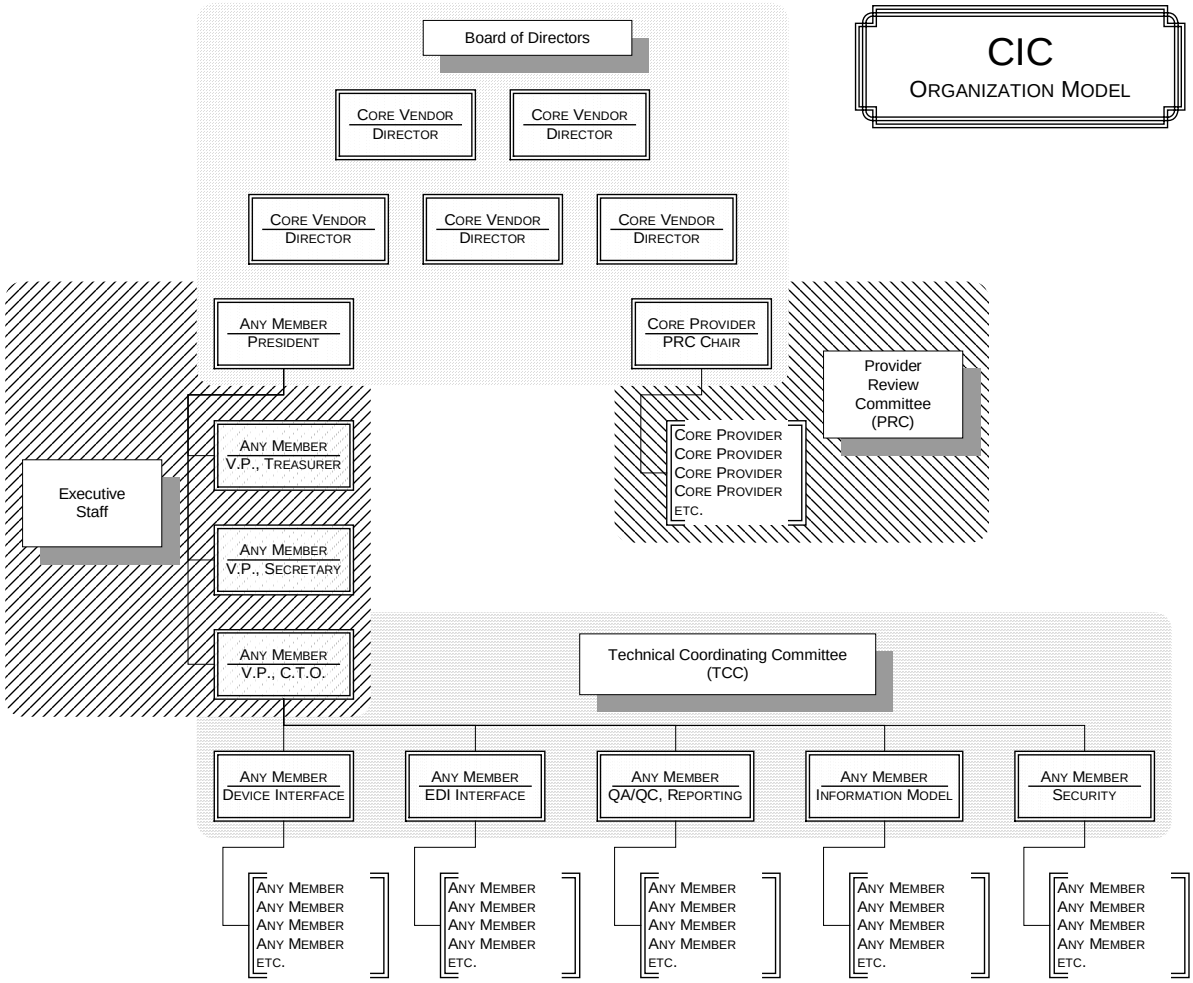


Figure 1: Connectivity Industry Consortium Organization Model

5.4.1 ADMINISTRATION

The CIC Executive Staff, with oversight by the Board of Directors, is responsible for (a) "running the railroad" to keep the work on schedule, (b) planning, (c) finance (retaining an accounting company for reporting and audits), (d) legal (including intellectual property management), (e) publications and distribution, and (f) promotion and information release.

5.4.1.1 Expected Time Requirements

It is anticipated that there will be one fulltime position, that of the Vice-President - Chief Technical Officer, who also serves as the Chair of the Technical Coordinating Committee. The role of the President may require a time commitment of about 20%. The responsibilities of this position can be shared with the three Vice-Presidents. The Vice-President - Secretary and Vice-President - Treasurer positions should involve not more

than 10% time commitment. In all cases, it is assumed that the Consortium will complete its work within 12 to 15 months.

5.4.2 TECHNICAL COMMITTEES

Each of the Technical Committees is composed of representatives of suppliers (diagnostic products, I/T) and providers. Although five committees are shown, the final number will be determined at the CIC kick-off meeting. An experienced technical professional from a supplier company heads each. The Technical Committee heads also serve as members on the Technical Coordinating Committee. Each Technical Committee is responsible for the part of the standard in its area of specialty.

5.4.2.1 Expected Time Requirements

Participants on the Technical Committees can expect to spend less than 10% of their time on CIC activities. We expect that the CIC workload will be greatest during the first two quarters, when the architecture and specifications will be defined. These estimates are derived from the following work model.

Table 5: Expected Time Requirements for Technical Committees

QUARTER	MEETINGS	PREPARATION	TOTAL
1	12, 1-hour ea.	4 hours/meeting	60 hours
2	12, 1-hour ea.	4 hours/meeting	60 hours
3	10, 1-hour ea.	3.5 hours/meeting	45 hours
4	10, 1-hour ea.	3 hours/meeting	40 hours
		Total:	**205 Hours**

5.4.3 TECHNICAL COORDINATING COMMITTEE

The mission of the Technical Coordinating Committee is to (a) consolidate and harmonize the output of the five Technical Committees to prepare a single, comprehensive standard, (b) work with the Provider Review Committee to gain user acceptance, and (c) gain the endorsement of the membership for implementation.

5.4.3.1 Expected Time Requirements

Members of the Technical Coordinating committee should expect to spend roughly 10% of their time on CIC-related activities. In addition to the workload as a member of a Technical Committee (5.4.2.1), the TCC will meet approximately bi-weekly. The TCC will also hold at least one meeting per quarter with the PRC to review the status of the CIC standards.

As always, every effort will be made to hold these meetings by electronic means. However, it is anticipated that the TCC will meet face-to-face at least three times during the lifetime of the Consortium.

5.5 CREATION OF THE ORGANIZATION

The CIC will be established early in January of 2000. Details of the process for creating the organization are given in Appendix I, the Consortium Bylaws. These steps can be summarized as follows:

1) Nominations are collected for the Board of Directors, the Technical Committees, the Administrative positions, and the Provider Review Committee.
2) The Bylaws are ratified by the participating organizations. After ratification, membership is 'frozen', until all positions have been elected.
3) Election of the Board of Directors – Core Vendor members shall nominate at least 10 candidates for the 5 elected positions. Each core vendor shall cast one vote, and the 5 candidates with the most votes constitute the Board.
4) The Board of Directors shall elect the President.
5) The Provider Review Committee shall elect a Chair.
6) The PRC Chair and the President join the Board of Directors, making it a seven-person body.
7) The Board of Directors elects the Vice-President – Chief Technical Officer.
8) The Board of Directors elects the Vice-President – Treasurer.
9) The Board of Directors elects the Vice-President – Secretary.
10) The Board of Directors elects the co-chairs of the Technical Committees.
11) The Board of Directors shall, as it deems necessary, appoint individuals or organizations as Advisors to the Board.

5.6 WORKFLOW AND DECISION MAKING

This section describes the decision process for proposing and approving standards and specifies the roles of the various committees of the CIC in this process. Figure 2 provides an overview of the process flow.

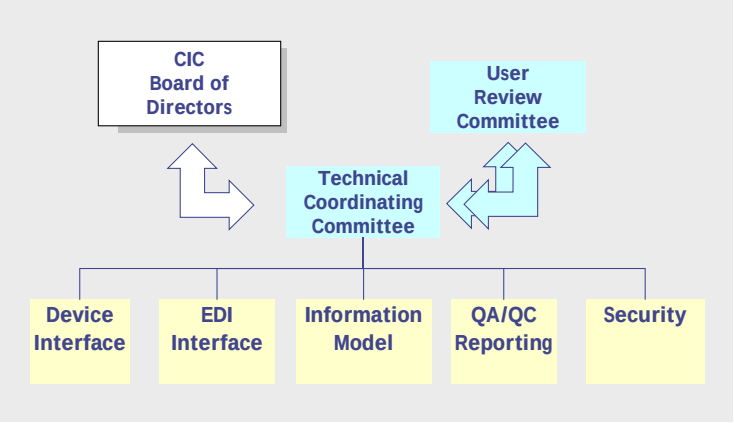


Figure 2: CIC Standards Development Process Flow

The Bylaws, included as Appendix I, describe in detail the Consortium's structure and operations. A brief overview is presented in this section.

5.6.1 PROPOSING STANDARDS

- Each Technical Committee develops proposals for standards in its designated technical area, approves them by 2/3 vote, and submits them to the Technical Coordinating Committee (TCC). Each Technical Committee member is entitled to the number of votes assigned to the category of membership of that member.
- The TCC reviews and consolidates the proposals and refers them to the Provider Review Committee (PRC).
- The PRC evaluates the proposals, based on Provider requirements and priorities, and submits suggested additions or changes to the TCC.
- The TCC incorporates the PRC suggestions and distributes the proposed standard(s) to its members for voting.

5.6.2 TECHNICAL COORDINATING COMMITTEE (TCC) VOTING

- TCC members vote on the proposed standard(s). Each member is entitled to a single vote.
- TCC members who enter a negative vote must document their reasons for the rejection. Lack of documentation will cause the vote to be treated as an abstention.
- Submission of the proposed standard(s) to the PRC requires the approval of 2/3 of the voting TCC members. Comments on negative votes must be referred to the PRC with the recommended standard(s).

5.6.3 PROVIDER REVIEW COMMITTEE (PRC) VOTING

- The PRC reviews the proposed standard(s) and votes to approve or reject the submission to the Consortium for a final ballot.
- Each PRC member is entitled to a single vote. Approval by 2/3 of the voting PRC members is required.
- If the PRC rejects the proposed standard(s), it is returned to the TCC along with comments on the reasons for the rejection.
- If the PRC approves the proposed standard(s), it is forwarded to the Board of Directors, to schedule the final Consortium ballot.

5.6.4 CONNECTIVITY INDUSTRY CONSORTIUM (CIC) VOTING

- The Board of Directors schedules a vote by all eligible CIC members on the recommended standards. The Chair of the TCC manages the balloting.
- The designated voting representative of each Member is entitled to cast the number of votes assigned to his/her organization's category of membership.
- Adoption of the standard by the CIC requires approval by 2/3 of the total votes.

5.7 INFORMATION MANAGEMENT, PUBLICATION, AND PROMOTION

The CIC Board of Directors and Executive Staff has the following responsibilities, relative to information management, publications and promotion:

(a) To inform the membership of the current status of the project

(b) To give the membership access to drafts of developmental standards

(c) To publish the final, formal version of the standard

(d) To promote the standard in the broad POC health care sector

(e) To select the appropriate standards-setting organization and negotiate the orderly transfer of the standard to insure maintenance and future enhancement.

6 TIME LINE

The Consortium's schedule lasts for 12 to 15 months. At the end of this period, the Consortium will have produced a working multi-vendor demonstration of core POC interoperability. The Consortium plans a 'sunset' phase at the end of the schedule, during which time the Consortium will transfer its work to one (or more) formal standards setting bodies (e.g. IEEE, HL7, ASTM).

6.1 MILESTONES AND DELIVERABLES

The milestones and deliverables for the Consortium will coincide with major industry meetings. The following dates illustrate the Consortium's major milestones and the associated industry meetings. When appropriate, Consortium meetings may be scheduled immediately prior to these industry events:

October 20, 1999: Consortium Kick-0ff Meeting - Redwood City, CA

- Structure of the Consortium
- Member buy-in and commitment
- IVD Vendors, IS companies, and Providers in alignment on structure, objectives and timeline

November 1999: Briefing for European Companies

- Held at Medica, November 17-20 - Duesseldorf, Germany
- Introduce consortium concept, objectives, structure and process

Mid-January, 2000: Consortium Launch Event

- Held at one of the following: (a) Chicago O'Hare Hyatt Regency, (b) San Diego, to coincide with HL7 Winter Working Group Meeting, (c) Palm Springs, to coincide with the Laboratory Automation conference.
- Consortium launch meeting
- Elect Consortium Board and Officers
- First organizational and planning meeting

April 2000: Milestone #1 – HIMSS, Dallas, Texas

- Preliminary architecture
- Presentation of concept

July 2000: Milestone #2 – AACC, San Francisco, CA

- Demonstrate preliminary interoperability solution
- Certification of concept
- Detailed architecture
- Start pilots

November 2000: Milestone #3 – Medica, Dusseldorf, Germany

- Operating multi-vendor demo
- Product announcements
- Show first results from pilots

6.2 PROPOSED TIMELINE

The Consortium will limit its lifetime to one-year. At the end of this period, it is anticipated that the work product of the Consortium will be transferred to a standards body (e.g. IEEE, ASTM, HL7) for maintenance.

Table 6: Connectivity Industry Consortium Timeline