ConCert by HIMSS™ Certification:
An Overview

This paper provides an introduction to the ConCert by HIMSS certification program. An overview of the 2015 Certification Pilot program is also provided along with information on the testing process, testing requirements and a list of existing participating vendors at the time of the HIMSS15 Annual Conference & Exhibition.
Table of Contents

1. Introduction to ConCert by HIMSS ......................................................... 2
2. DIRECT and IHE Components of the Certification Program ..................... 3
3. Certification Process and iPatientCare Case Study .................................. 5
4. The Interoperability Test Tool (ITT) ...................................................... 6
5. Conclusion ......................................................................................... 8
Introduction to ConCert by HIMSS™

Introduced at HIMSS15, ConCert by HIMSS is a comprehensive interoperability testing and certification program, built upon the work of the EHR|HIE Interoperability Workgroup (IWG), IHE USA and now governed by HIMSS. ICSA Labs serves as the testing and certification body for this effort.

ConCert offers a one-of-a-kind, vendor-independent seal of approval for electronic health record (EHR), health information services provider (HiSP) and health information exchange (HIE) systems. Setting a bar higher than Meaningful Use, products that pass this robust, highly automated certification program will verify that, once certified, a health IT system is capable of exchanging health information securely and reliably with other certified systems.

ConCert certification focuses squarely on interoperability and clinical data exchange, so the specifications tested relate to securely transmitting clinical information using IHE Cross Enterprise Document Sharing (XDS) and DIRECT, as well as patient and provider identification and matching (PIX, PDQ, HPD). The certification program is targeted to specific products and versions of health IT available in the marketplace, whether they are an EHR module, edge system, HiSP or HIE. By leveraging constrained specifications and an automated test tool the certification program provides assurance that ConCert certified EHRs and HIEs will be able to securely and reliably exchange information. There are three certifications available, ConCert EHR, ConCert HIE and ConCert HiSP. Vendors successfully completing the certification testing will receive one or more of the certification marks shown below.

What is the value of ConCert by HIMSS to healthcare providers?

As health information technology and interoperability standards evolve, it's never been more important or more challenging to protect an organization’s investment in information systems. Backed by trusted leaders including IWG, IHE USA and HIMSS, the ConCert program streamlines the certification of interoperability in health IT and helps healthcare providers evaluate vendor claims, simplifying the task of selecting the right information systems for their organization. Dedicated to transparency, collaboration, and vendor-independence, the ConCert mark is the certification healthcare providers can trust to be assured that technologies are vetted to a high standard of excellence and will truly result in seamless integration between software products and systems that will serve their organization well now and in the future.

What is the value of ConCert by HIMSS to vendors?

As an independent program backed by trusted leaders in advancing health information technology, testing and certification, including HIMSS, the ConCert mark identifies vendors that are leading providers of interoperable health IT solutions, helping them stay ahead of the competition. ConCert certification allows a vendor to lower the cost of custom interface development and focus their efforts on product innovation. As a well-governed and transparent collaboration of stakeholders with the goal of advancing progress in interoperability between health IT and health information assets, a ConCert mark of approval allows providers to be assured that the products they purchase are interoperable with other products.
2 DIRECT and IHE Components of the Certification Program

The ConCert by HIMSS certification includes a combination of requirements for both point-to-point and query-based exchange. The certification program requirements are based on the functional and technical specifications developed by the IWG, a group of industry stakeholders— including 19 forward-thinking states and 47 EHR and HIE vendors—all dedicated to developing interoperability standards that enable secure and reliable connectivity. The IWG specifications leverage the IHE ITI Technical Framework and the DIRECT Project specifications. These specifications will continue to evolve and be updated as the program matures. Below is additional information on some of the specific IHE profiles and DIRECT standards included in each of the three certifications, EHR, HIE and HISP.

What is Query-Based Exchange?
To replace paper and fax machines “push” based standards like DIRECT were created. Query-based exchange is “pull” based exchange where providers can search and retrieve a specific set of information.

What is IHE and DIRECT?
IHE, Integrating the Healthcare Enterprise, is an initiative by healthcare professionals and industry to improve the way systems in healthcare share information. For more information on IHE and the specifications included in the ConCert by HIMSS program please visit http://www.ihe.net/IT_Infrastructure/
The DIRECT Project provides standards for the push of health information from a sender to a known receiver, similar to how an email or fax is pushed from one endpoint to another. For more information on the DIRECT Project please visit http://wiki.directproject.org/

ConCert by HIMSS EHR, ConCert by HIMSS HIE and ConCert by HIMSS HISP
The ConCert EHR certification focuses on both point-to-point and query-based interoperability pulling from the following catalog of specifications:

- Patient Identifier Cross Referencing (“PIX”): Patient Identity Source/Consumer
- Patient Demographics Query (“PDQ”): Patient Demographics Consumer
- Audit Trail and Node Authentication (“ATNA”): Secure Node/Secure Application
- DIRECT Project SMTP Secure Health Transport
- Cross Enterprise Document Media Interchange (“XDM”): Portable Media Creator/Portable Media Importer
- Healthcare Provider Directory (“HPD”): Provider Information Source, Provider Information Consumer

ConCert by HIMSS Approved HIE
The ConCert HIE certification focuses on query-based interoperability by pulling from the following catalog of specifications:

- Patient Identifier Cross Referencing (“PIX”): Patient Identifier Cross-reference Manager
- Patient Demographics Query (“PDQ”): Patient Demographics Supplier
- Audit Trail and Node Authentication (“ATNA”): Secure Node/Secure Application
ConCert by HIMSS Approved HISP
The ConCert HISP certification focuses on point-to-point interoperability by pulling from the following catalog of specifications:

- DIRECT Project SMTP Secure Health Transport
- Cross Enterprise Document Media Interchange (“XDM”): Portable Media Creator/Portable Media Importer
- Cross Enterprise Document Reliable Interchange (“XDR”): Document Recipient

More information including the current technical specifications and sample lists of tests can be found at www.himssinnovationcenter.org/concert.

The figures below demonstrate how the certification program drives EHR, HIE and HISP vendors toward secure and reliable interoperability.

Figure 1-1  DIRECT and Query-Based Exchange
Certification Process and iPatientCare Case Study

The ConCert by HIMSS certification has initiated a pilot program that will include up to twenty participants comprised of a mix of EHR, HIE and HISP systems. The pilot is scheduled to be completed by December 1, 2015. Vendors successfully completing the certification testing will receive one or more of the following seals:

The certification process for the ConCert program begins with an application to ICSA Labs. Once all contracting documents have been executed, the vendor is asked to complete a questionnaire that contains information necessary to create their account in the Interoperability Test Tool (ITT) designed by Stella Technology. A call is then scheduled to demonstrate how to use the test tool, and the vendor is put in a pre-testing or Practice status. During the pre-testing phase, the vendor actively tests their system using the ITT to ensure compliance with the IWG functional and technical requirements. Should questions arise, those are submitted to ICSA Labs for evaluation and response. Once all pre-testing is completed successfully, the official certification test can be scheduled with ICSA Labs.

“The pre-testing process was definitely helpful. Even in all our past certification experiences like the ONC MU program, we have always done a lot of pre-testing and rehearsals prior to our certification. The practice mode in the ITT allowed us to be certain that we were well-prepared and that there would be no surprises during the certification testing process.”

Arnaz Bharucha, Senior Technology Officer at iPatientCare

Certification tests are primarily conducted remotely using web conferencing tools, though in some circumstances testing may occur at special events onsite at the HIMSS Innovation Center in Cleveland, Ohio. During the certification test, the vendor will demonstrate how their system complies with each of the required ITT test cases while being observed by an ICSA Labs test proctor. The length of the test is dependent upon the volume and complexity of required test groups which are based on the type (EHR, HIE, HISP) of system being certified. The level of preparedness of the vendor also directly drives how long certification testing will take. Once all testing has been completed successfully, the test results are submitted to ICSA Labs’ internal Certification Body for an independent evaluation. After certification has been granted, all certification marks, logos, and other marketing materials are supplied to the vendor for use in marketing their product as ConCert certified.

One of the first products to complete testing in this program was an EHR system developed by iPatientCare, Inc. The product had previously tested at an IHE Connectathon and was certified as a Complete Ambulatory and Complete Inpatient EHR under the ONC Health IT 2011 Edition and 2014 Edition Certification Programs. While some of the IHE specifications covered new ground, the product development team had extensive experience working with and developing health information exchanges, patient portals, and core clinical EHR applications. Leveraging this experience, they thoroughly prepared themselves for the certification by undergoing extensive, self-paced pre-testing to discover and iron out any issues as early as possible. The resources they extended during the pre-testing phase enabled them to fully understand how the testing tool worked, and even suggest improvements to the tool developer to improve the overall reporting and workflow of the ITT. Having this level of experience and entering the testing so well-prepared allowed iPatientCare’s team to complete ConCert EHR certification testing in just over two hours.

“We are very happy and proud for being one of the first vendors to certify as part of the ConCert by HIMSS™ certification program. We believe this is a significant achievement of iPatientCare, in line with its goals of being a high achiever and thought-leader in this space that will contribute in creating a real and lasting impact in making interoperability a reality in healthcare.”

Udayan Mandavia, CEO, iPatientCare
The Interoperability Test Tool (ITT)

A majority of the testing is automated through the Interoperability Test Tool (ITT). This modular tool was built to provide an intuitive user experience along with the necessary underlying architecture to support certification testing programs.

The ITT’s test management module provides the System Under Test’s (SUT) testing and development team the ability to track progress of testing while in Practice or Certification mode. The SUT is able to select which mode they are operating in on a configuration screen in the ITT. The Practice mode allows the SUT to run through all required and optional tests for the test groups configured as many times as desired. This provides an opportunity for the SUT to discover and correct issues, and to implement the best solution instead of a “quick fix.” This preparedness is vital and provides the SUT confidence that their certification testing will be a success.

The ITT is a “smart” tool, similar to a smart phone, by providing a combination of functionality to meet the needs of the SUT. The ITT provides simulation of production interoperability configuration, advanced user experience design, low and high level technical validation, and testing progress management, including the enablement of communication between the SUT and test managers.

The tool provides real-time feedback, aiding vendors in resolving issues in a pre-production environment. This is an important benefit as the transaction responses from the ITT are consistent and predictable, allowing all SUTs participating to configure to the same common interoperability targets. Having EHRs, HIEs and HISP vendors all testing their products against the same tool provides the ability to achieve a certified ecosystem of connected products.

“The ITT provides the necessary transactional detail to quickly identify and resolve issues. Any time more information and more processes reviewing the data that is being exchanged can be provided, the more is learned about the deep workings of what it is to be an EHR operating in an interoperability landscape. This paves the way for future integration successes.”

Robert Barker, Vice President of Community Connectivity Solutions, NextGen Healthcare

The ITT fulfills the role of the integration partner system to the SUT whether that role is as an EHR, HIE or HISP system. For that reason the ITT is structured to support the following three test groups:

- **EHR** – Tests both query-based and DIRECT exchange capabilities.
- **HIE** – Tests the infrastructure systems ability to receive and provide documents to an edge system. Query-based exchange testing only, no DIRECT testing.
- **HISP** – DIRECT testing only, no query-based exchange testing.

The tool provides real-time feedback, aiding vendors in resolving issues in a pre-production environment. This is an important benefit as the transaction responses from the ITT are consistent and predictable, allowing all SUTs participating to configure to the same common interoperability targets. Having EHRs, HIEs and HISP vendors all testing their products against the same tool provides the ability to achieve a certified ecosystem of connected products.
The figure below shows how the ITT interacts with the different vendor systems during the testing process.

The ITT is an excellent tool designed to automate the validation of compliance to the ConCert testing requirements. The result of the testing is confidence that a ConCert certified EHR will securely and reliably exchange information with a certified HIE and/or another certified EHR.
Conclusion

Much work has been accomplished to date by the IWG membership through stakeholder engagement, standards development and ratification, industry and government support, and the definition and design of an industry-changing certification program. The next step in this journey is the realization of the certification program through the launch of ConCert by HIMSS.

All stakeholders involved are confident that the ConCert program is setting a new standard by offering a one-of-a-kind, vendor-independent seal of approval for EHR and HIE systems. Setting a bar higher than Meaningful Use, products that pass this robust, highly automated certification program will verify that, once certified, a health IT system is capable of exchanging health information securely and reliably with other certified systems.

Join these industry leading vendors that are participants in the ConCert 2015 Certification Pilot program.

Attributions
Authors: Vinny Sakore, ICSA Labs; Tone Southerland, Ready Computing
Contributors: John Baus, HIMSS; Robert Barker, NextGen Healthcare; Arnaz Bharucha, iPatientCare; John Donnelly, Intepro; Anuj Desai, New York eHealth Collaborative; Michelle Knighton, ICSA Labs; Alex Lippitt, HIMSS; Udayan Mandavia, iPatientCare; Joyce Sensmeier, HIMSS; Amit Trivedi, ICSA Labs