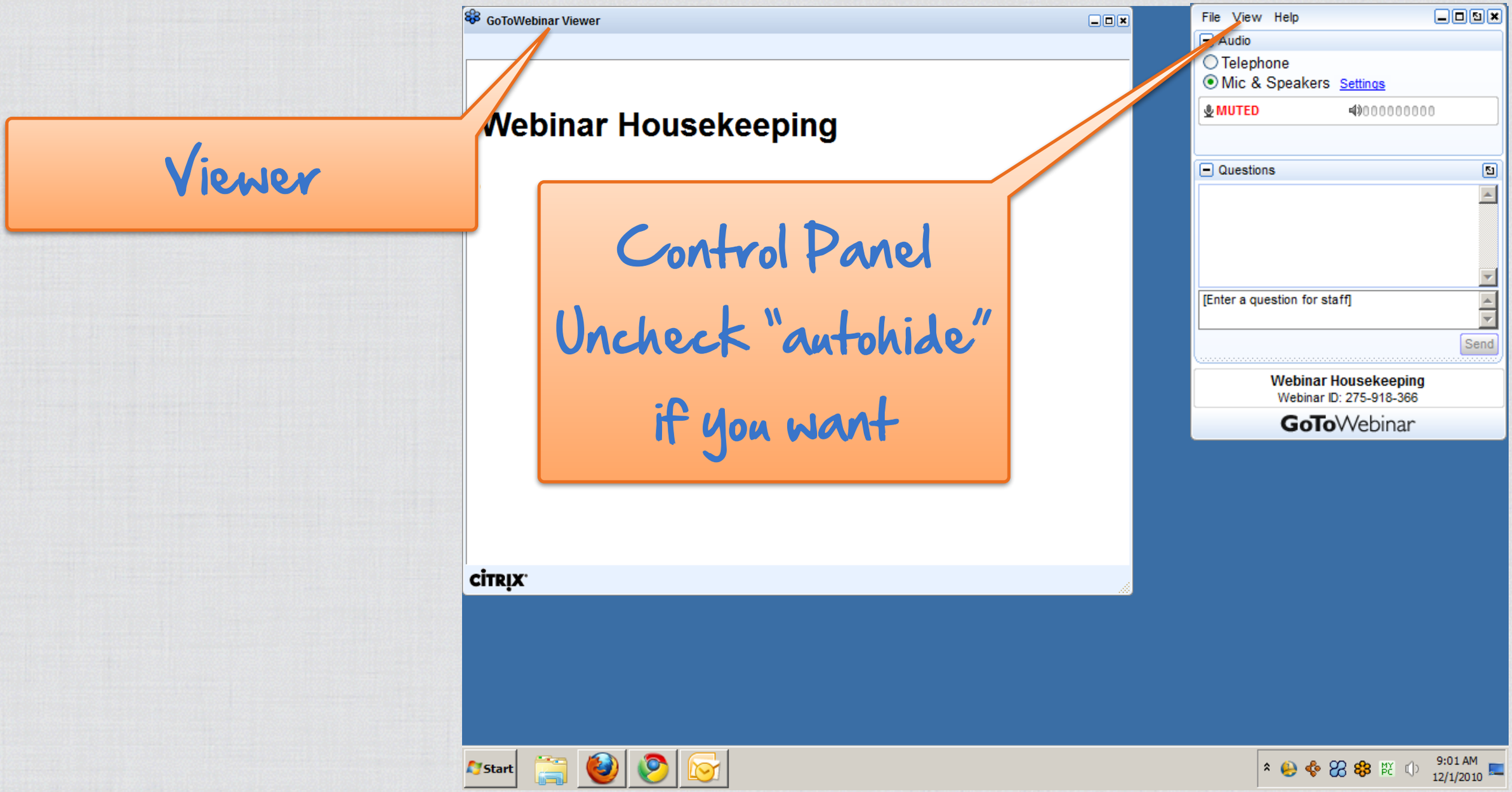
Webinar Logistics

A few housekeeping details so you can make the most out of today's session

What You See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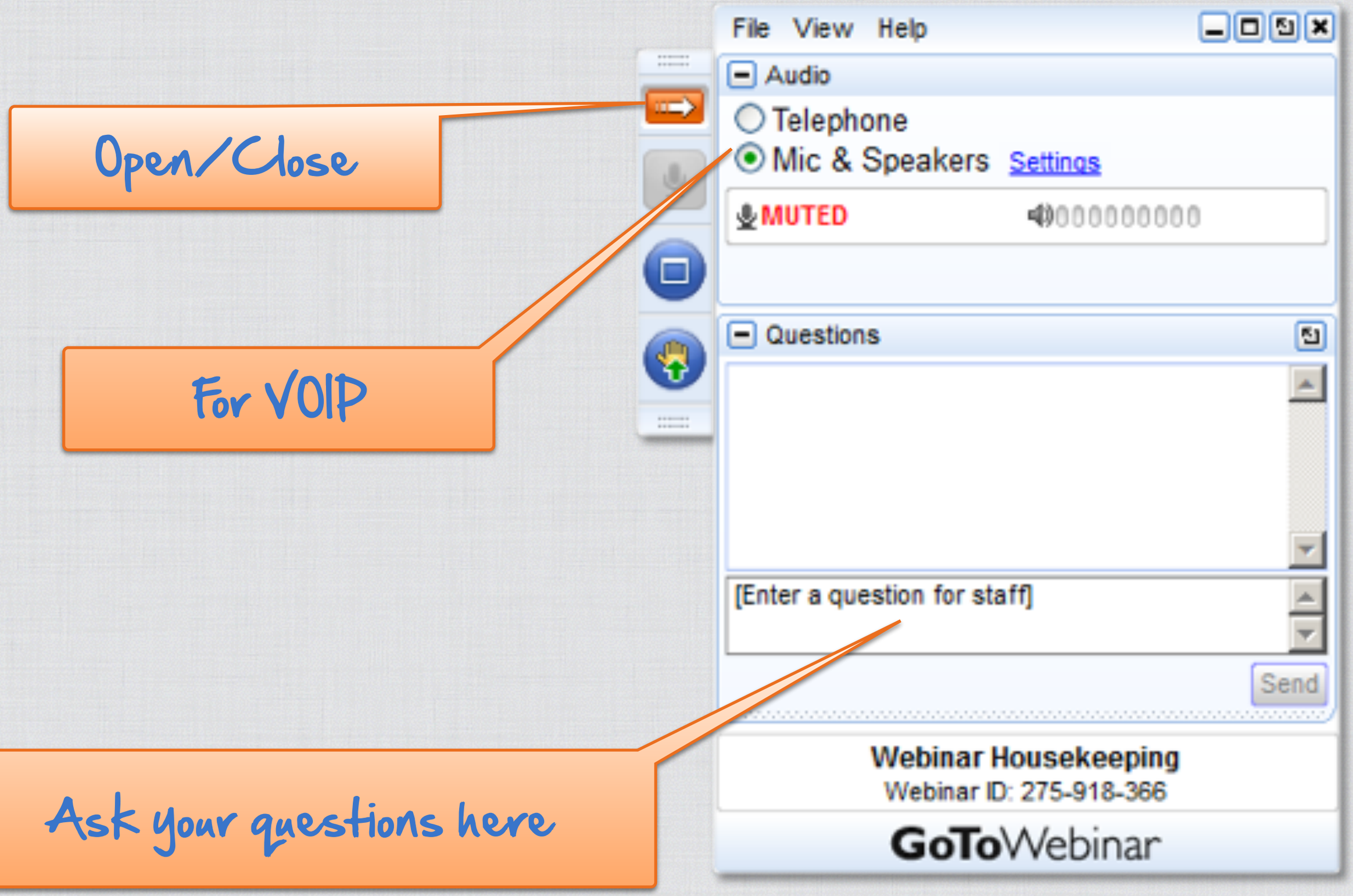
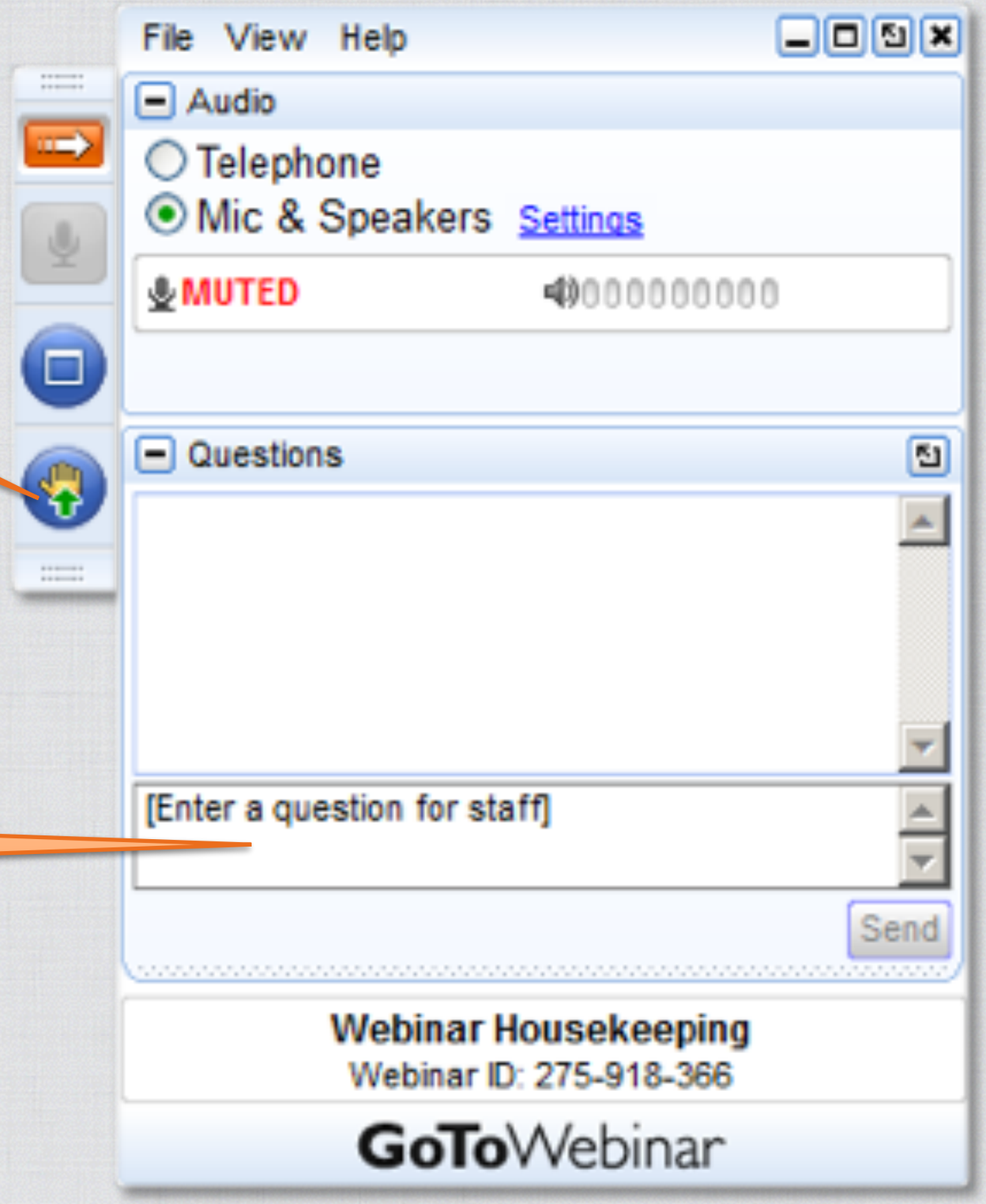


Discussion

Raise Hand

Can also ask questions/ comments to RI staff here



If you have webinar troubles…

tmpritch@regenstrief.org

Laboratory LOINC Workshop - Indianapolis, IN USA

LOINC® from Regenstrief

Updates on LOINC

Daniel J. Vreeman, PT, DPT, MSc

Associate Research Professor, Indiana University School of Medicine
Associate Director for Terminology Services, Regenstrief Institute, Inc

@djvreeman

INDIANA UNIVERSITY
DEPARTMENT OF MEDICINE
School of Medicine

Regenstrief Institute
Center for Biomedical Informatics
Better Care. Better Health.

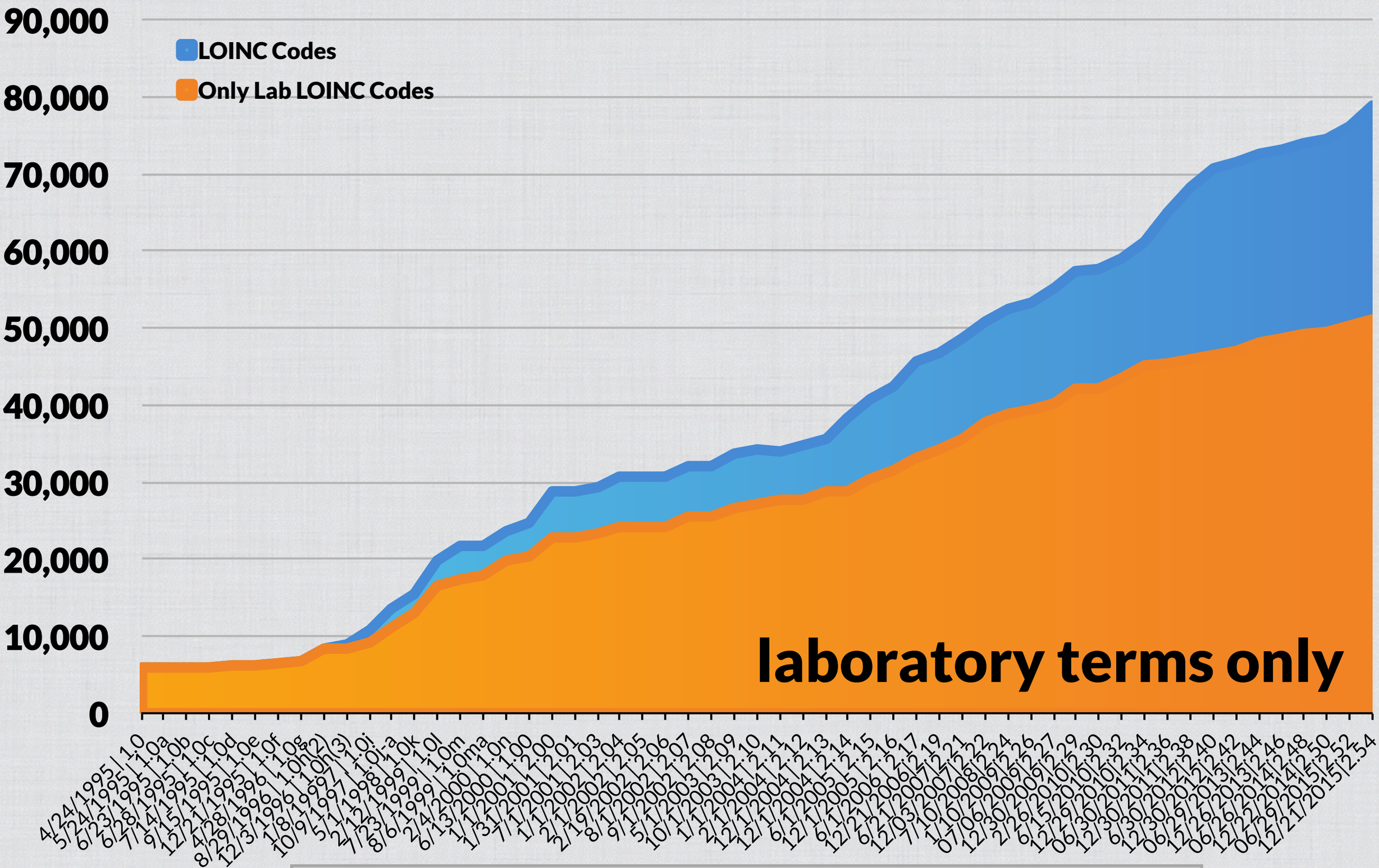
Overview

1. Growth and adoption
2. Key publications and presentations
3. Highlights and discussion of recent US Federal initiatives

photo via Vernio77

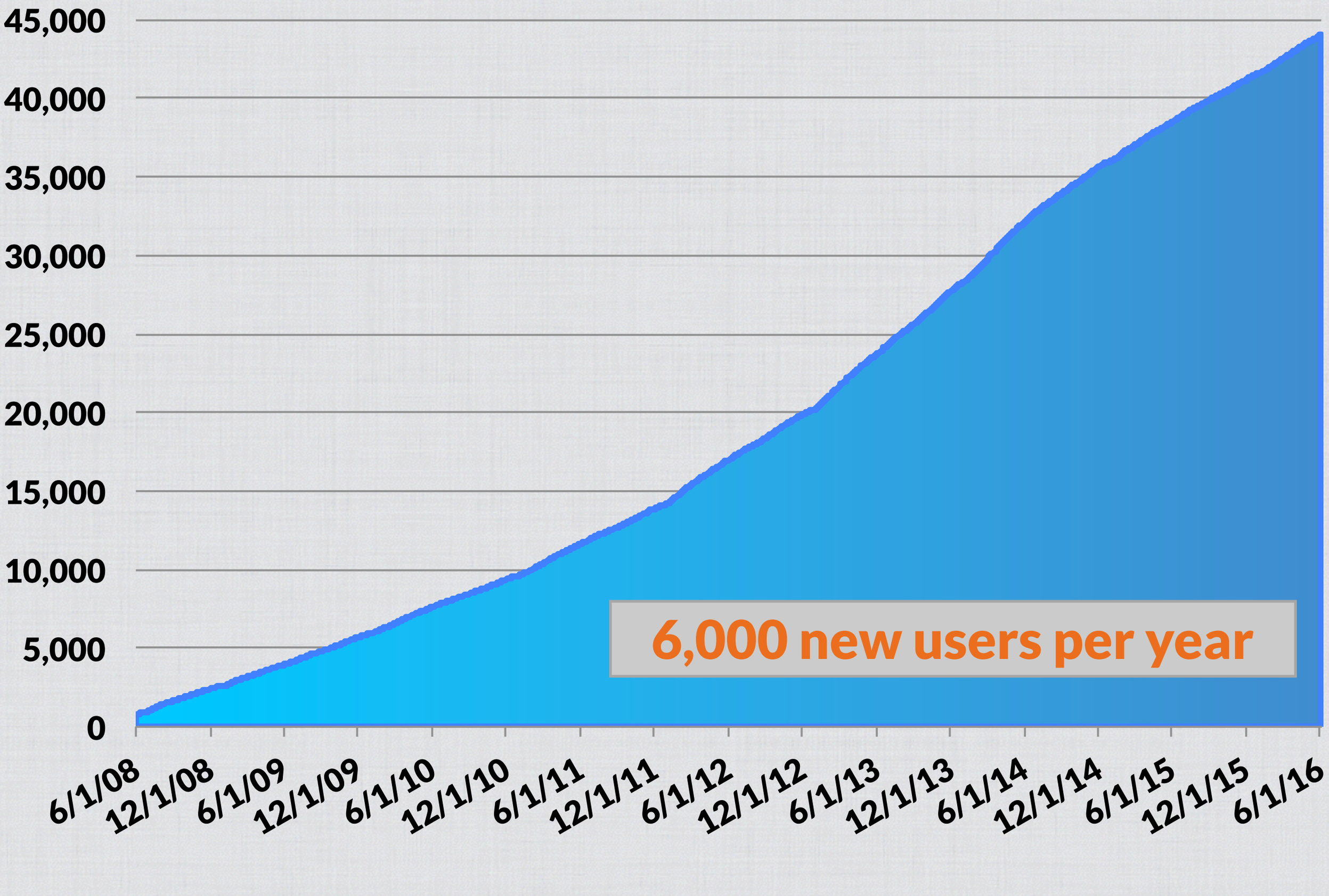
44,100+ registered users in 171 countries

LOINC Codes Over Time by Release

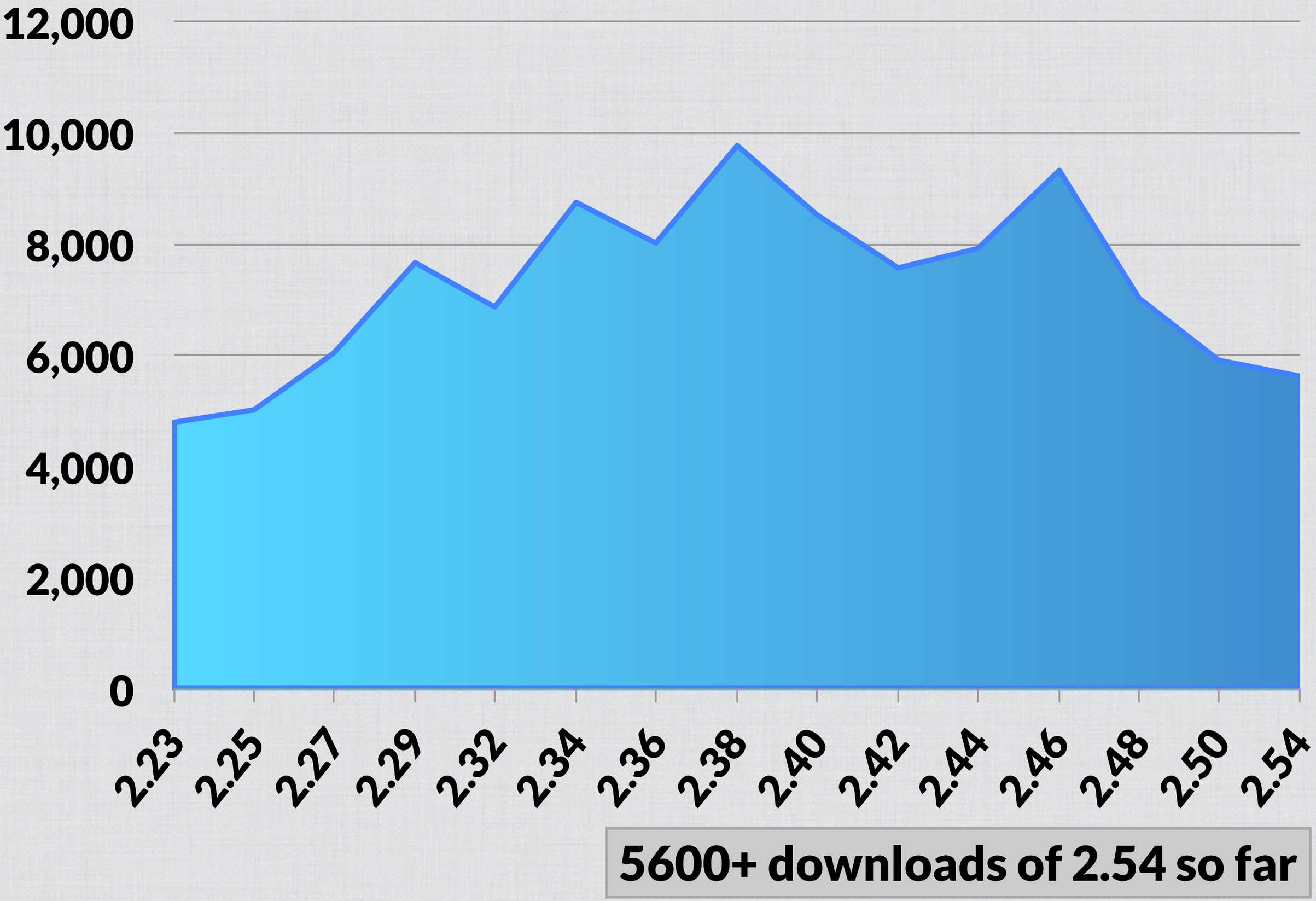


1700+ new terms in upcoming release

loinc.org registered users

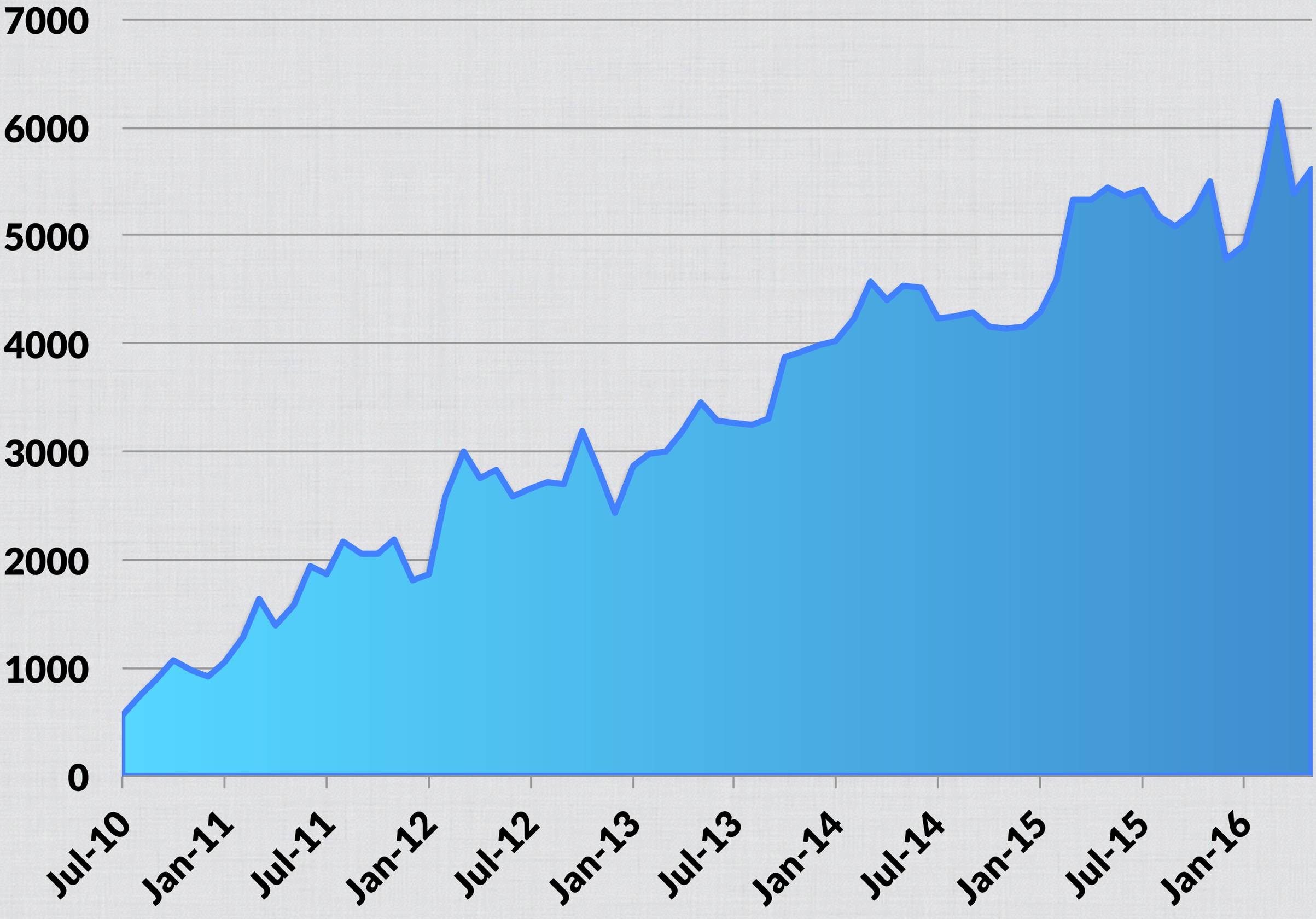


LOINC Downloads By Release



5600+ downloads of 2.54 so far

search.loinc.org unique visitors



A note about this past development cycle

Special welcome and introduction of our newest LOINC team members

Tim Briscoe

Katie Allen

Mary Zabriskie

Sara Armson (transition to content development)

Support for a larger team the result of increased external funding success

Content development team has done a remarkable job tackling our backlog of term requests

Our target is processing all requests received 3 months out of a release date

We have a large body of pending work in non-lab areas

We're Hiring!

We have a systems engineer positions available and an entry-level content developer position open.

If you know people who'd be great LOINCers, send them my way!

loinc.org/jobs

Key Publications and Presentations

Now available!

danielvreeman.com/loinc-essentials

PCORnet Best Practices Webinar

Top 10 Tips for Mapping to LOINC

Daniel J. Vreeman

Extended recommendations available:

https://danielvreeman.com/top-10-tips-for-mapping-to-loinc/

NCVHS

Recommendations on Attachment Standards

Daniel J. Vreeman

My comments / recommendations available:

https://danielvreeman.com/recommendations-to-ncvhs-on-attachment-standards/

FDA Adoption and Promotion of LOINC

January 27, 2015

May 14, 2015

September 28, 2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–N–0451]

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 038

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a publication containing modifications the Agency is making to the list of standards FDA recognizes for use in premarket reviews (FDA Recognized consensus standards) that sponsors may use to support marketing applications. The modifications to the list of recognized standards are intended to assist those who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit either electronic or written comments concerning this document at any time. See section VII of this document for the effective date of the recognition of standards announced in this document.

ADDRESSES: An electronic copy of Recognition List Number: 038 is available on the Internet at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm*. See section VI of this document for electronic access to the searchable database for the current list of FDA recognized consensus standards, including Recognition List Number: 038 modifications and other standards related information.

Submit written requests for single copies of this document to the Division of Consumer Education, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149.

Submit electronic comments on this document to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Scott A. Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3632, Silver Spring,

TABLE 2—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS—Continued

Recognition No.	Title of standard [1]	Reference No. and date
	J. Software/Informatics	
13–70	Application of risk management for IT-networks incorporating medical devices—Part 2–5: Application guidance—Guidance on distributed alarm systems.	IEC TR 80001–2–5 2014.
13–71	Logical Observation Identifiers Names and Codes (LOINC)	LOINC 2.48 2014–06–27.
	Part 10425: Device Specialization—Continuous Glucose Monitor (CGM).	
	K. Sterility	
14–456	Packaging for terminally sterilized medical devices—Guidance on the application of ISO 11607–1 and ISO 11607–2.	ISO/TS 16775 First edition 2014–05–15.

[1] All standard titles in this table conform to the style requirements of the respective organizations.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-1349]

Electronic Study Data Submission; Data Standards; Support for the Logical Observation Identifiers Names and Codes

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is encouraging sponsors and applicants to provide Logical Observation Identifiers Names and Codes (LOINC) codes (available at http://loinc.org/) for clinical laboratory test results in investigational study data provided in regulatory submissions submitted to the Center for Drug Evaluation and Research and to the Center for Biologics Evaluation and Research. LOINC code is defined as electronic messages for laboratory test results and clinical observations. The decision to adopt LOINC for lab test results is part of a larger FDA effort to align the use of data standards for clinical research with ongoing nationwide health information technology initiatives. FDA invites public comment on appropriate steps the Agency could take to promote the use and utility of LOINC-coded clinical data submitted to the Agency. The LOINC common terminology will be listed in the FDA Data Standards Catalog that is posted to FDA's Study Data Standards Resources Web page at

Workshops & Conferences (Medical Devices)

2015 Medical Device Meetings and Workshops

2014 Medical Device Meetings and Workshops

Medical Device Webinars and Stakeholder Calls

Public Workshop FDA/CDC/NLM Workshop on Promoting Semantic Interoperability of Laboratory Data, September 28, 2015

The Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and the National Library of Medicine (NLM) of the National Institutes of Health are announcing the following public workshop titled "FDA/CDC/NLM Workshop on Promoting Semantic Interoperability of Laboratory Data."

The purpose of the workshop was to receive and discuss input from stakeholders regarding proposed approaches to promoting the semantic interoperability of laboratory data between *in vitro* diagnostic devices and database systems, including laboratory information systems and electronic health records.

- Discussion Paper
- Date, Time and Location
- Federal Register Notice
- Webcast

Stay tuned for follow-up meeting this Fall

November

Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices

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Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.
Document issued on: January 26, 2016

Submit comments and suggestions regarding this draft document within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document regarding CDRH-regulated devices, email them to: DigitalHealth@fda.hhs.gov;
For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach and Development (OCOD), by calling 1-800-835-4709 or 240-402-8010

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

ONC 2016 Interoperability Standards Advisory

2016 Interoperability Standards Advisory

Office of the National Coordinator for Health IT

Best Available Standards and Implementation Specifications

My Take

Additional characteristics about maturity and adoption are nice

Fails to acknowledge the common question/answer paradigm of much data

There are other domain areas with clear interoperability needs and mature vocabulary standards available

The CDSIC additions are bizarre and would be disruptive

Clem, Susan Matney, and myself are on the HITSC ISA 2017 Task Force

FEDERAL REGISTER

Meaningful Use Stage 3

Part II

Department of Health and Human Services

Office of the Secretary

45 CFR Part 170

2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications; Final Rule

FEDERAL REGISTER

Vol. 80 Friday,
No. 200 October 16, 2015

87 mentions of LOINC.

Part II

Department of Health and Human Services

Office of the Secretary

45 CFR Part 170

2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications; Final Rule

Social, Psychological, and Behavioral Data

Financial resource strain

Education

Stress

Depression

Physical activity

Alcohol use

Social connection and isolation

Exposure to violence

All have specific LOINC codes identified

Work in behavioral/mental health data standards is percolating

New HL7 WG being discussed, recent Health Affairs paper

French LOINC Adoption

« Les éléments de l'identification qui figurent sur l'étiquette apposée sur le prélèvement sont définis par le laboratoire dans le cadre de ses procédures préanalytiques. Le numéro d'identification du patient fait partie de ces éléments.

« Lors de la transmission d'un échantillon dans le cadre des dispositions de l'article L. 6211-19, les deux laboratoires s'assurent de la traçabilité du prélèvement par le numéro d'identification du patient.

« *Art. D. 6211-3.* – I. – Le résultat de l'examen de biologie médicale est validé par un biologiste médical avant toute communication.

« Le nom et le prénom du biologiste médical apparaissent en toutes lettres sur le résultat communiqué de l'examen.

« II. – L'interprétation contextuelle du résultat mentionnée aux articles L. 6211-2 et L. 6211-19 consiste à écrire la signification biologique d'un ou de plusieurs résultats, pris individuellement ou dans leur ensemble, en fonction des éléments cliniques pertinents. L'interprétation contextuelle peut être postérieure à la validation du résultat dans les cas de décision thérapeutique urgente ou dans les périodes de permanence de l'offre de biologie médicale. Elle est réalisée dans le même temps que la validation dans les autres cas. L'interprétation comporte la signature du biologiste médical.

« III. – Les résultats validés du ou des examens de biologie médicale et leur interprétation contextuelle figurent dans un compte rendu qui comporte les éléments mentionnés à l'article D. 6222-3, les éléments d'identification mentionnés à l'article D. 6211-2, l'identification du ou des biologistes médicaux signataires. Le compte rendu reprend les principaux éléments pertinents du contexte clinique. Lorsque des résultats sont communiqués de façon partielle, le compte rendu porte la mention "résultat partiel" ou "résultats partiels".

« IV. – La communication appropriée du résultat au prescripteur et au patient se fait, pour chaque examen, dans le délai que permettent les données acquises de la science pour la phase analytique, en urgence si nécessaire. Le laboratoire est organisé de façon telle que les délais de rendu en urgence sont respectés pour toutes les situations médicales qui le nécessitent.

« V. – La communication du compte rendu au prescripteur s'effectue par la voie électronique.

« La communication du compte rendu au patient s'effectue par la voie électronique ou, à sa demande, sur support papier.

« *Art. R. 6211-4.* – Le compte rendu des examens de biologie médicale est structuré conformément au référentiel d'interopérabilité dénommé "volet compte rendu d'examens de biologie médicale", pris en application du quatrième alinéa de l'article L. 1111-8. L'identification et l'authentification du biologiste médical sont réalisées conformément aux référentiels mentionnés à ce même alinéa. Ce compte rendu structuré est produit, conservé et échangé par voie électronique conformément aux référentiels d'interopérabilité et de sécurité arrêtés par le ministre chargé de la santé après avis du groupement d'intérêt public chargé du développement des systèmes d'information de santé partagés mentionné à l'article L. 1111-24.

« Lorsque le compte rendu des examens de biologie médicale est communiqué au prescripteur par voie électronique, l'échange se fait en utilisant une messagerie électronique sécurisée de santé. Dès lors qu'il contribue à la coordination des soins, le compte rendu des examens de biologie médicale est inséré dans le dossier médical personnel mentionné à l'article L. 1111-14.

« *Art. D. 6211-5.* – Un arrêté du ministre chargé de la santé détermine la nature des échantillons à conserver après la réalisation de la phase analytique ainsi que la durée et les conditions de conservation de ces échantillons. En cas de transmission d'un échantillon, le laboratoire qui a la responsabilité de la réalisation des examens du patient au sens de l'article L. 6211-19 s'assure que le laboratoire qui réalise la phase analytique respecte cette disposition dans ses procédures.

French law mandating LOINC for identifying lab tests via IHE XD-LAB profile

We are breaking for lunch until 1pm