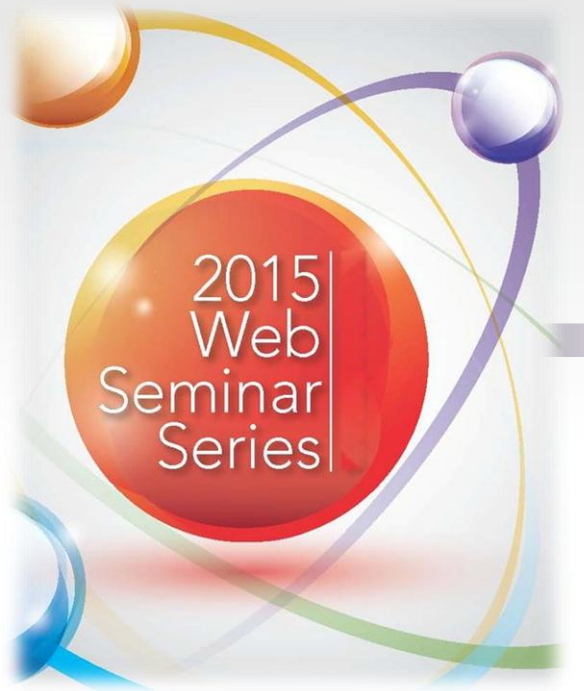

Electronic Medical/Health Records - Common Data Elements for Substance Use Disorders

Betty Tai, PhD
Director, NIDA CTN

Robert Gore-Langton, PhD
Principal Investigator, The Emmes Corporation

CTN WEB SEMINAR SERIES:
A FORUM TO EXCHANGE RESEARCH KNOWLEDGE
Produced by: CTN Training
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NIDA CTN Web Seminar Series

November 2015

Emmes

Electronic Medical/Health Records - Common Data Elements for Substance Use Disorders

Robert Gore-Langton, PhD
Principal Investigator
The Emmes Corporation, Rockville, MD

Many Perspectives for EHRs

Emmes

- **Practitioners and Patients**
  - CEO/CIO (administration, cost savings)
  - Medical Director and Clinicians (quality improvement)
  - Various Healthcare Personnel (quality care, efficiency)
  - Vendors and Technical Personnel (product maintenance)
  - Patients (better health decisions, better health, security)
- **My perspective (full disclosure ☺)**
  - PI in a Clinical Research Organization (better research)
  - Consultant to NIDA on EMR/EHR (better SUD research)

NIDA CTN's interest in EHRs and CDEs

Emmes

2010 -

- **Realization that data elements for Substance Use Disorders (SUDs) are not generally being included in EHRs and there is no process in place to standardize these data elements**
- **Failure to standardize data collection will limit the value for data exchange in clinical care and for EHR-based clinical research on SUDs**

Urgency for SUD data collection

Emmes

- **1983-2004: 32-fold increase in fatal medication errors at home related to alcohol and/or street drugs (Phillips DP et al. *Arch Intern Med* 208;168(14):1561-1566)**
- **1991-2009: 3-fold increase in opioid analgesic Rx's**
- **2005-2009: 2-fold increase in ER visits due to non-medical use of Rx opioids**
  - Rx opioid overdose now 2nd leading cause of unintentional death in U.S. (CDC: "national epidemic")
  - 2009: 5.25 million people in U.S. reported non-medical use of Rx painkillers
- **2013: Drug overdose leading cause of injury death**

Webinar learning objectives

- **Define differences between EMRs and EHRs**
- **Explain use of CDEs in clinical care and clinical research**
- **Outline the role of CDEs for Substance Use Disorders in an integrated vision of clinical care and research**

Brief History of Clinical Information Systems

Emmes

- **Computers** – clinical data management (late 1950s)
- **Hospital systems** – HIS, ADT, LIS, billing/accounting, pharmacy, radiology and pictures, nursing, practice management, chart/medical records management, …
- **1991 (25 years ago) – IOM landmark report:**

"The Computer-Based Patient Record: An Essential Technology for Health Care"

Evolving electronic records

Emmes

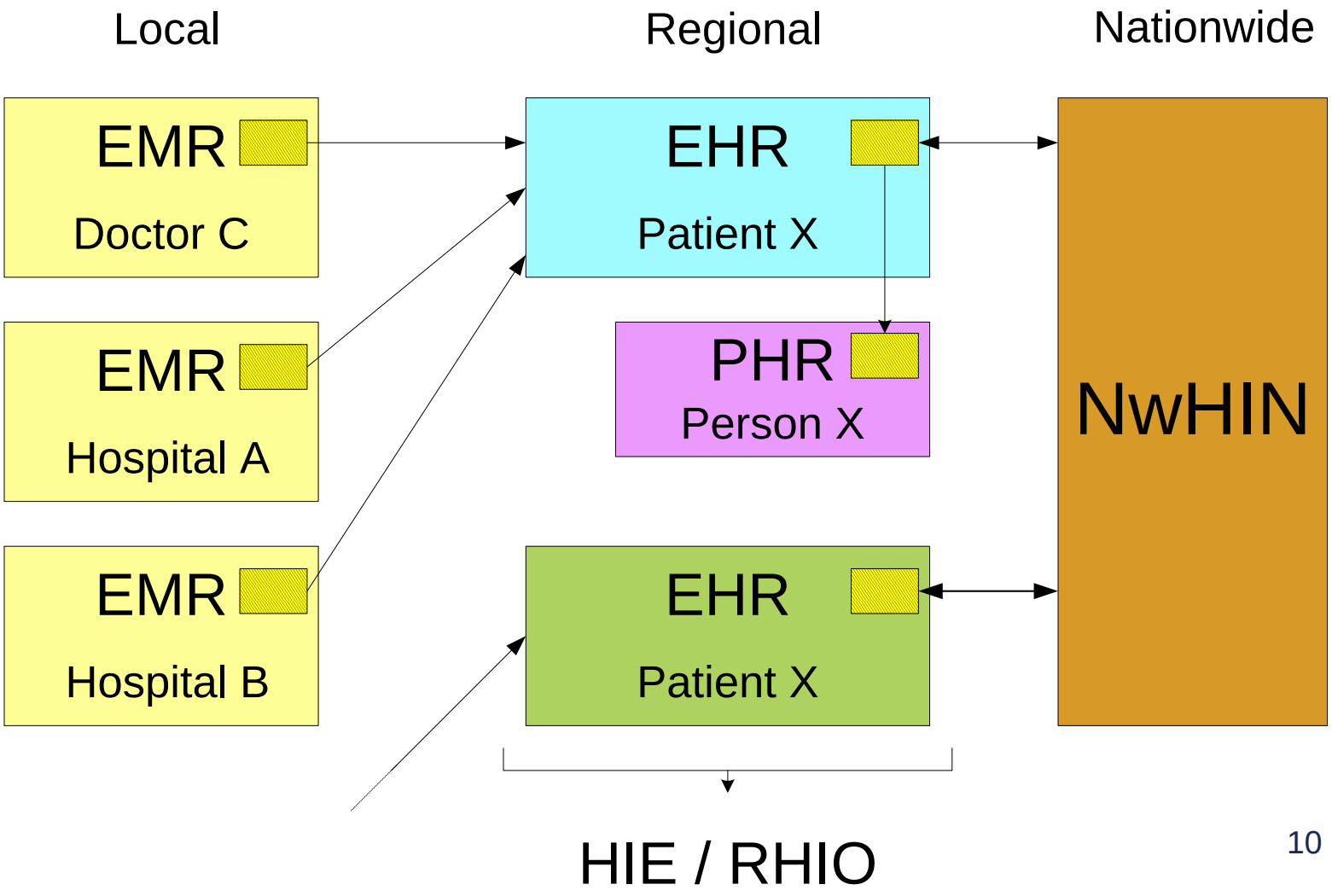
- **Computer-based patient record (CPR):** "electronic patient record that resides in a system designed to support users through availability of complete and accurate data, practitioner reminders and alert, clinical decision support systems, links to bodies of medical knowledge, and other aids." **(i.e., IOM concept)**
- **Ambulatory Medical Record**
- **Electronic Medical Record (EMR)**
- **Electronic Health Record (EHR)**
- **Individual/Personal Health Record (IHR/PHR) –**

virtualized record for individuals to access/manage/share information

What is different about an EHR?

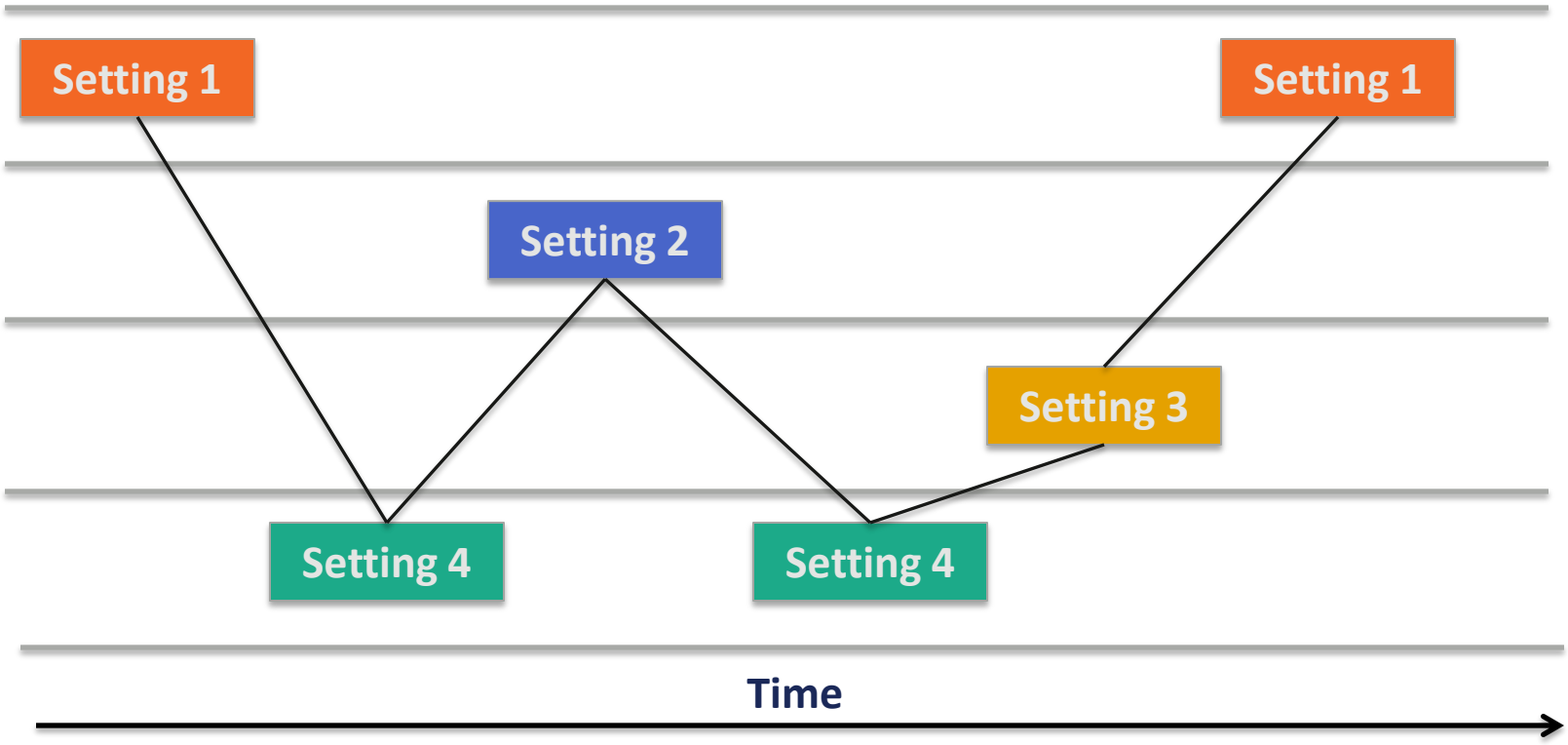
Emmes

- **CPR – a "concept" with unique coding of individually searchable data items**
- **EMR/EPR – only requires data in electronic form; hospital or practice-based**
- **EHR – "Key Capabilities of EHR Systems" defined by IOM in 2003:**
  - Longitudinal collection of electronic health information
  - Immediate electronic access (patient or population level)
  - Knowledge and decision-support (quality, safety, efficiency)
  - Share patient's complete health records (the ideal)
  - Efficiency for health care delivery


Local
Regional
Nationwide
EMR
Doctor C
EMR
Hospital A
EMR
Hospital B
EHR
Patient X
PHR
Person X
EHR
Patient X
NwHIN
HIE / RHIO

Longitudinal Records that follow you through life

Emmes

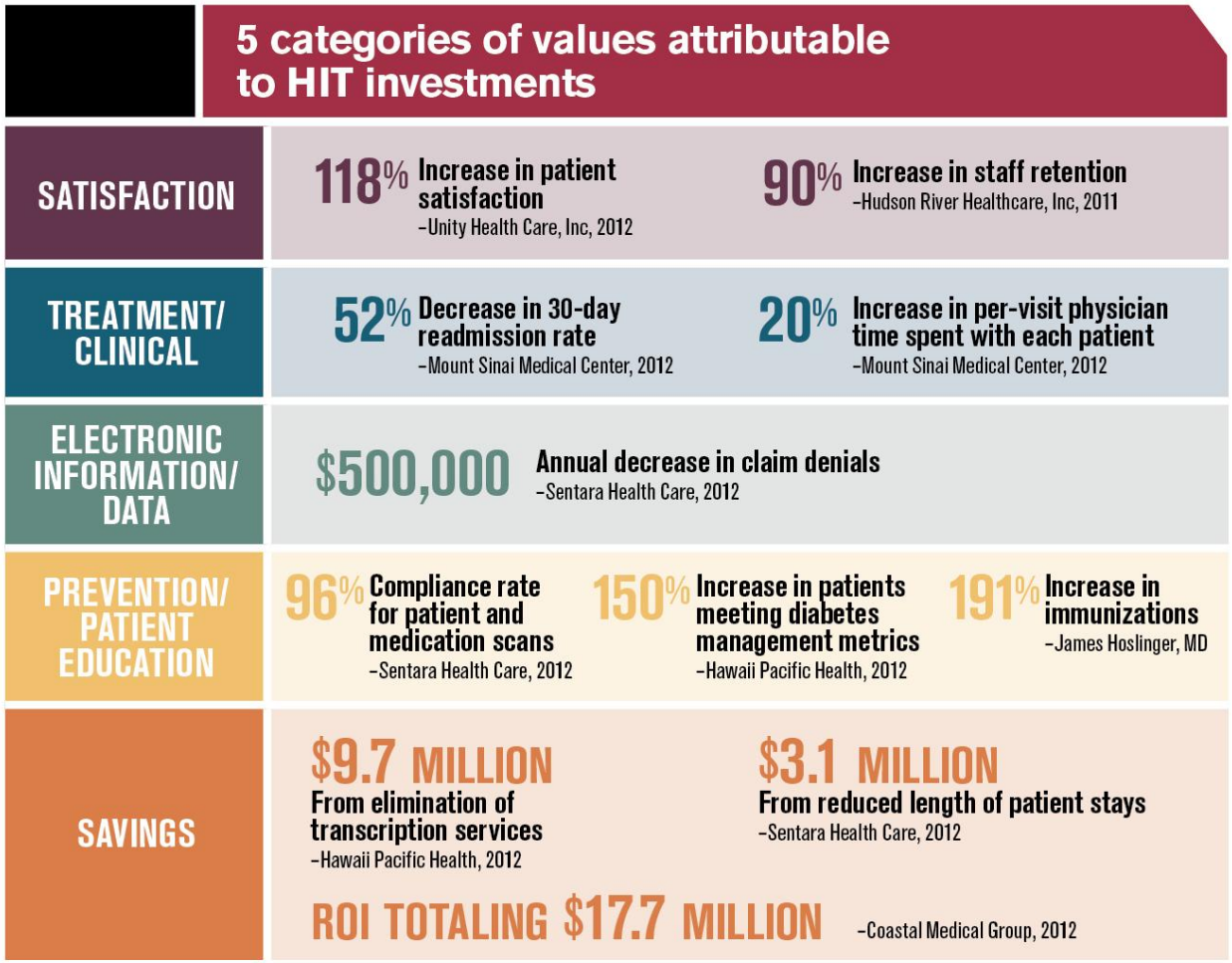


Anticipated Benefits of HIT-EHR

Improved health care – quality, safety, cost

- For the Patient
  - *Increased overall quality/ accuracy / fewer medical errors*
  - *Fewer redundant medical tests (reduced utilization)*
  - *Improved emergency care (fast access to records)*
  - *More accessible (increased delivery)/better transparency*
  - *Some say better privacy and security*
- For the Population / Country / State
  - *More efficient processing (system-wide **cost savings; billions)***
  - *Public health monitoring & management*
  - *Accelerate clinical research - "continuously learning health care system" (IOM)*
  - *For SUD, EHR could replace PDMPs (although no evidence it will)*

Values attributed to HIT/EHR investments



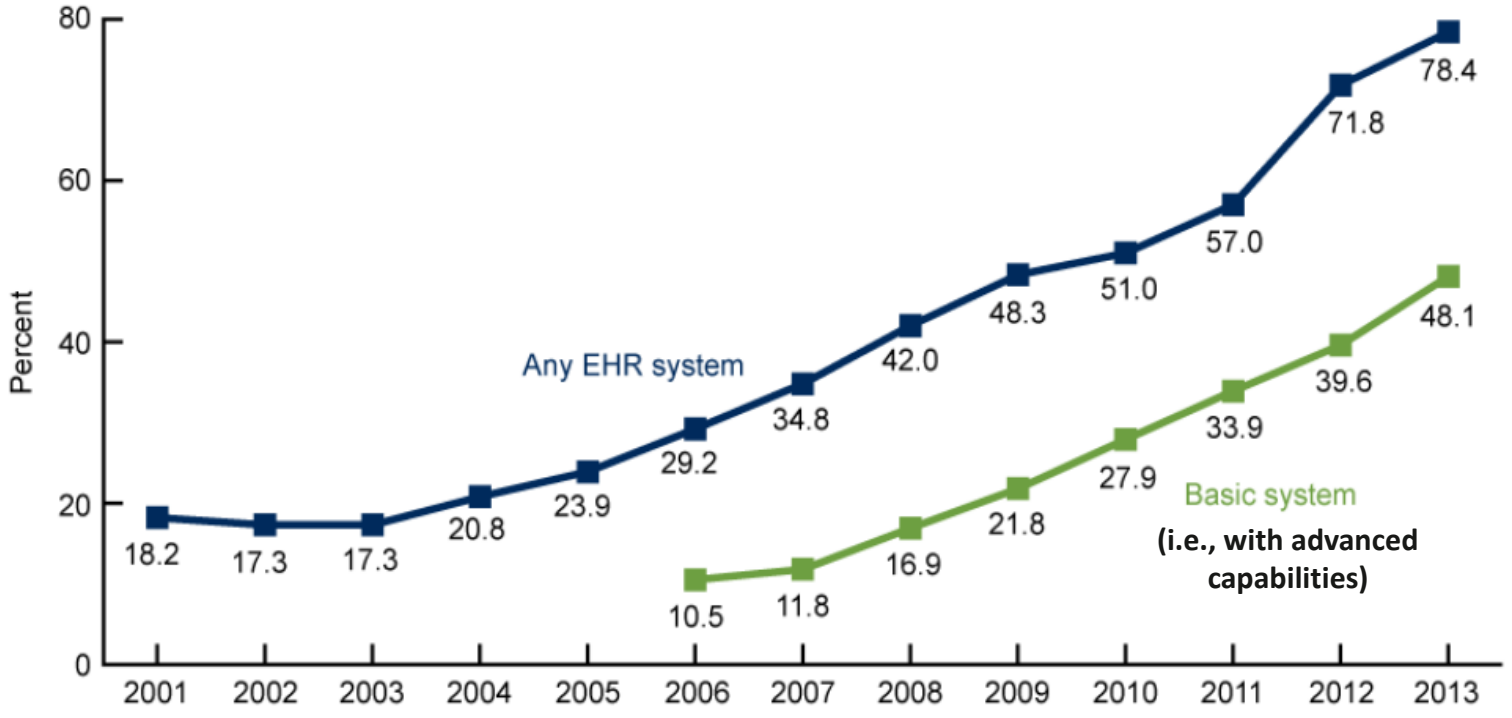
Source: HIMSS.org[1]

1. The HIMSS health IT value suite. http://www.himss .org/ValueSuite. Accessed August 19, 2013

EHR Adoption - Physicians

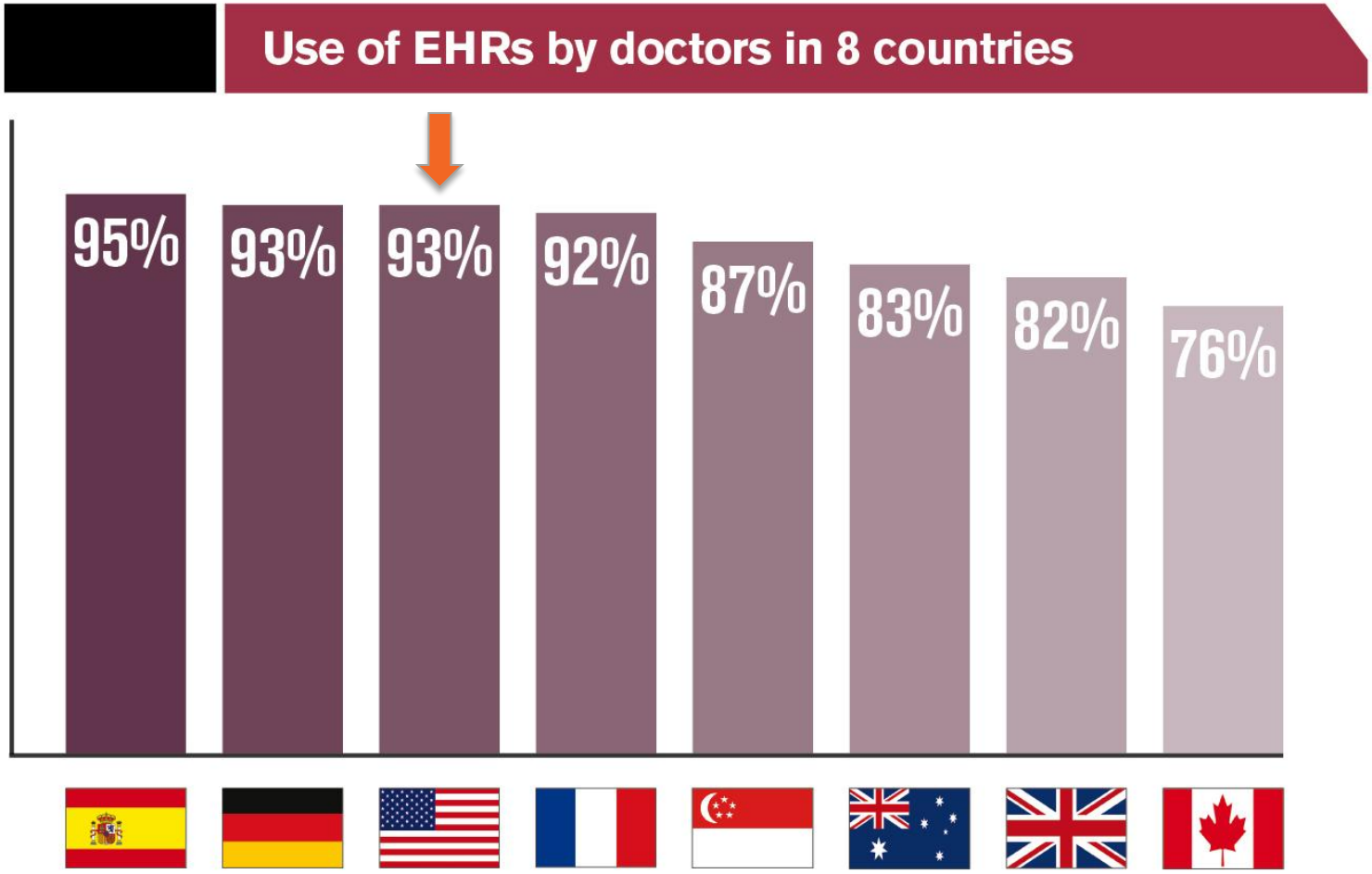
Emmes

EHR adoption among US office-based physicians, 2001-2013



Note: Data include nonfederal, office-based physicians and exclude radiologists, anesthesiologists, and pathologists.
Source: CDC/NCHS, National Ambulatory Medical Care Survey and National Ambulatory Medical Care Survey, Electronic Health Records Survey.
NCHS Data Brief No 143 http://www.cdc.gov/nchs/data/databriefs/db143.htm

Physician EHR Adoption (May 2013)



Source: Accenture[3]

3. EMR and HIE use increases among U.S. doctors, Accenture annual survey finds. May 9, 2013. http://newsroom.accenture.com/news/emr-and-hie-use-increases-among-us-doctors-accenture-annual-survey-finds.htm. Accessed August 19, 2013.

Barriers to EHR Implementation

- **High implementation costs – Ultimate beneficiaries uncertain. Poor integration with cost models.**
- **Liabilities related to privacy and security (HIPAA, 42 CFR part 2)**
- **Choosing appropriate software, and vendor lock-in**
- **Usability, training, high failure rates**

<u>Offsets to barriers</u>:

- CMS Meaningful use incentives – financial support through ARRA 2009 (HITECH Act) - $13 billion by Q1 2013; Medicaid/Medicare incentives per eligible provider
- Health Information Exchange (HIE) funding
- Regional Extension Centers (REC) – technical support

Federal Leadership for EHRs

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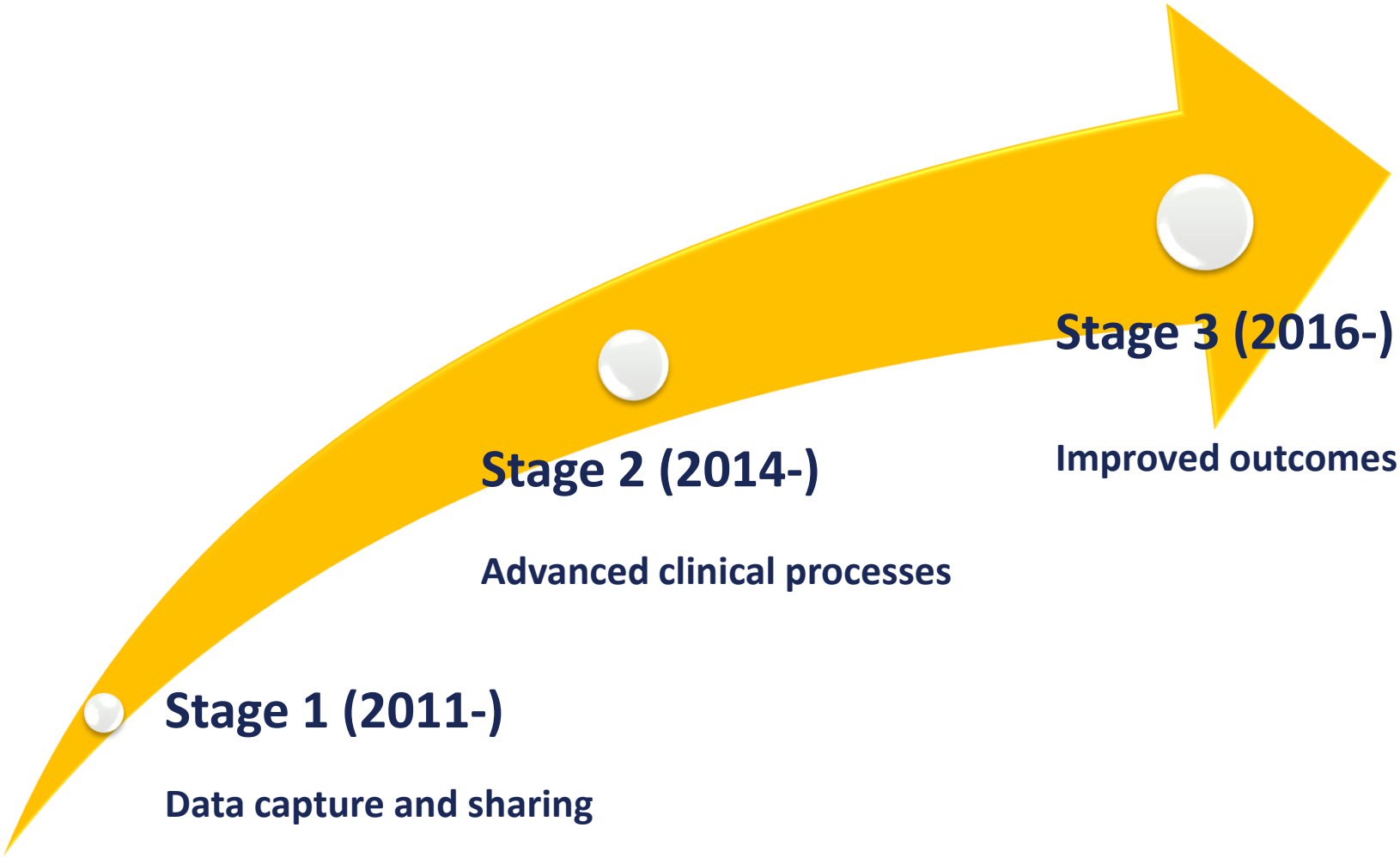
Some examples:

- **ONC HIT-EHR Strategic Plan (2008-2012)**
- **ONC Nationwide Health Information Network (NwHIN, a set of specifications) and NwHIN Exchange (public-private partnership data exchange)**
- **VA's VistA HIS architecture – public domain**
- **CCHIT – certification for HIT-EHR; 1 of 6 entities**
- **CMS Meaningful Use Program**

CMS Meaningful Use Program



What makes an EHR "Meaningful"?

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Stage 1: Meaningful use criteria focus on:	Stage 2: Meaningful use criteria focus on:	Stage 3: Meaningful use criteria focus on:
Electronically capturing health information in a standardized format	More rigorous health information exchange (HIE)	Improving quality, safety, and efficiency, leading to improved health outcomes
Using that information to track key clinical conditions	Increased requirements for e-prescribing and incorporating lab results	Decision support for national high-priority conditions
Communicating that information for care coordination processes	Electronic transmission of patient care summaries across multiple settings	Patient access to self-management tools
Initiating the reporting of clinical quality measures and public health information	More patient-controlled data	Access to comprehensive patient data through patient-centered HIE
Using information to engage patients and their families in their care		Improving population health

https://www.healthit.gov/providers-professionals/how-attain-meaningful-use

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What and Why of CDEs?

ISO 11179 Metadata Registry International Standard

Data Element + Metadata

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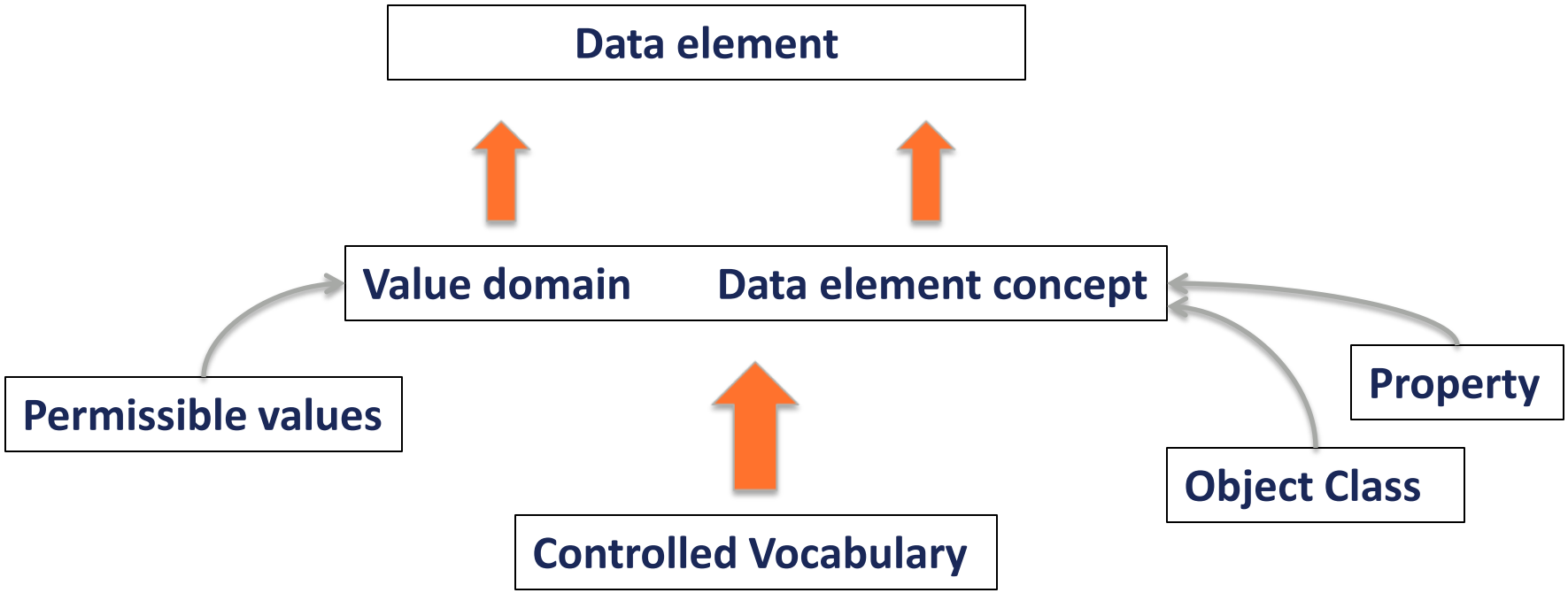

Standards for Interoperability

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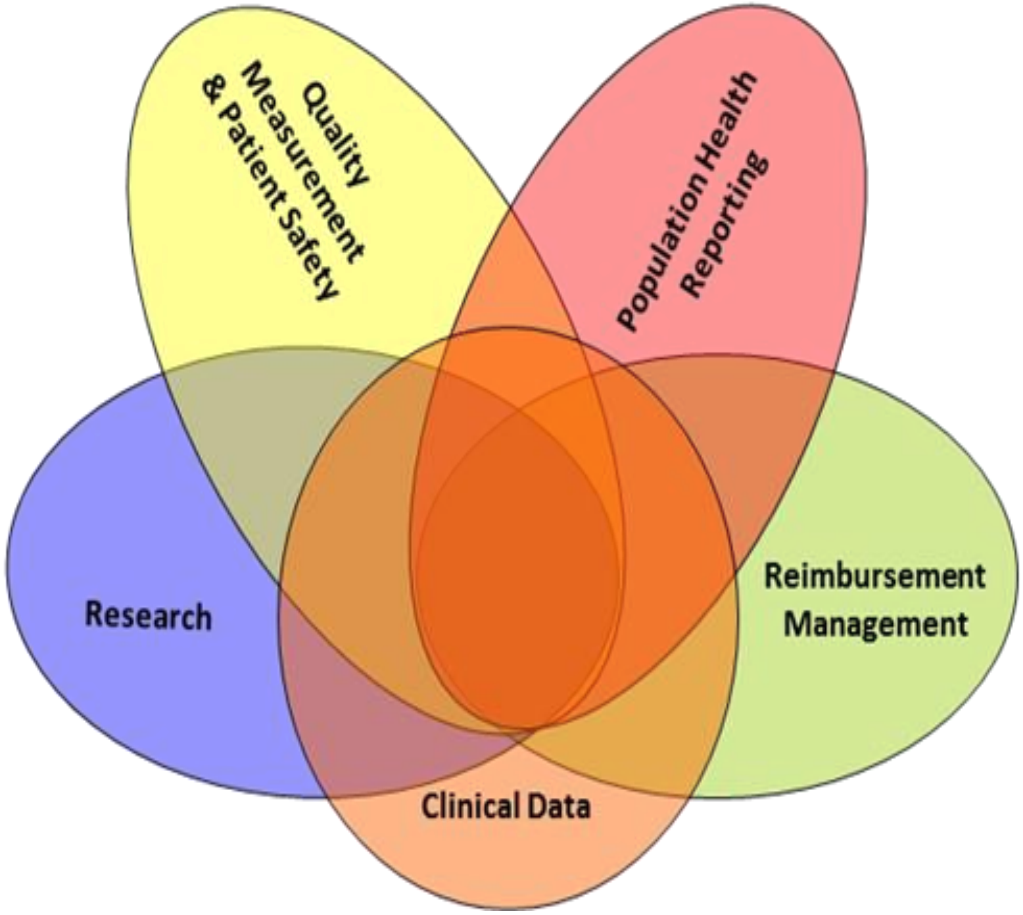
- **Semantic** (meaning of data is the same for system A and system B)
- **Syndactic/Technical** (electronic data exchange from system A to system B; ONC leadership)
- **Process** (business processes at A and B are compatible)

Collect Once, Use Many Times[1]



1. R.L. Richesson, C. Kallem, D. DuLong et al., 2011. Project White Paper – Common Data Elements for Clinical Documentation and Secondary Use: Diabe-DS Proof-9of-Concept for "Collect Once, Use Many Times"

Where does the data come from?

Emmes

- **Clinical research (databases, notes)**
- **Clinical trials (electronic data capture systems)**
- **Healthcare (paper records, EMRs, EHRs)**

PROBLEM is integrating data across multiple systems and standards

General objectives of CDEs

Emmes

Harmonize, standardize, simplify data collection -

- **Identify discrete, defined items for data collection (ISO/IEC 11179 metadata registry standard)**
- **Promote consistent data collection in the field**
- **Eliminate unneeded/redundant data collection**
- **Promote consistent reporting and analysis**
- **Reduce possibility of error due to data translation and transmission**
- **Facilitate data sharing (semantic interoperability)**

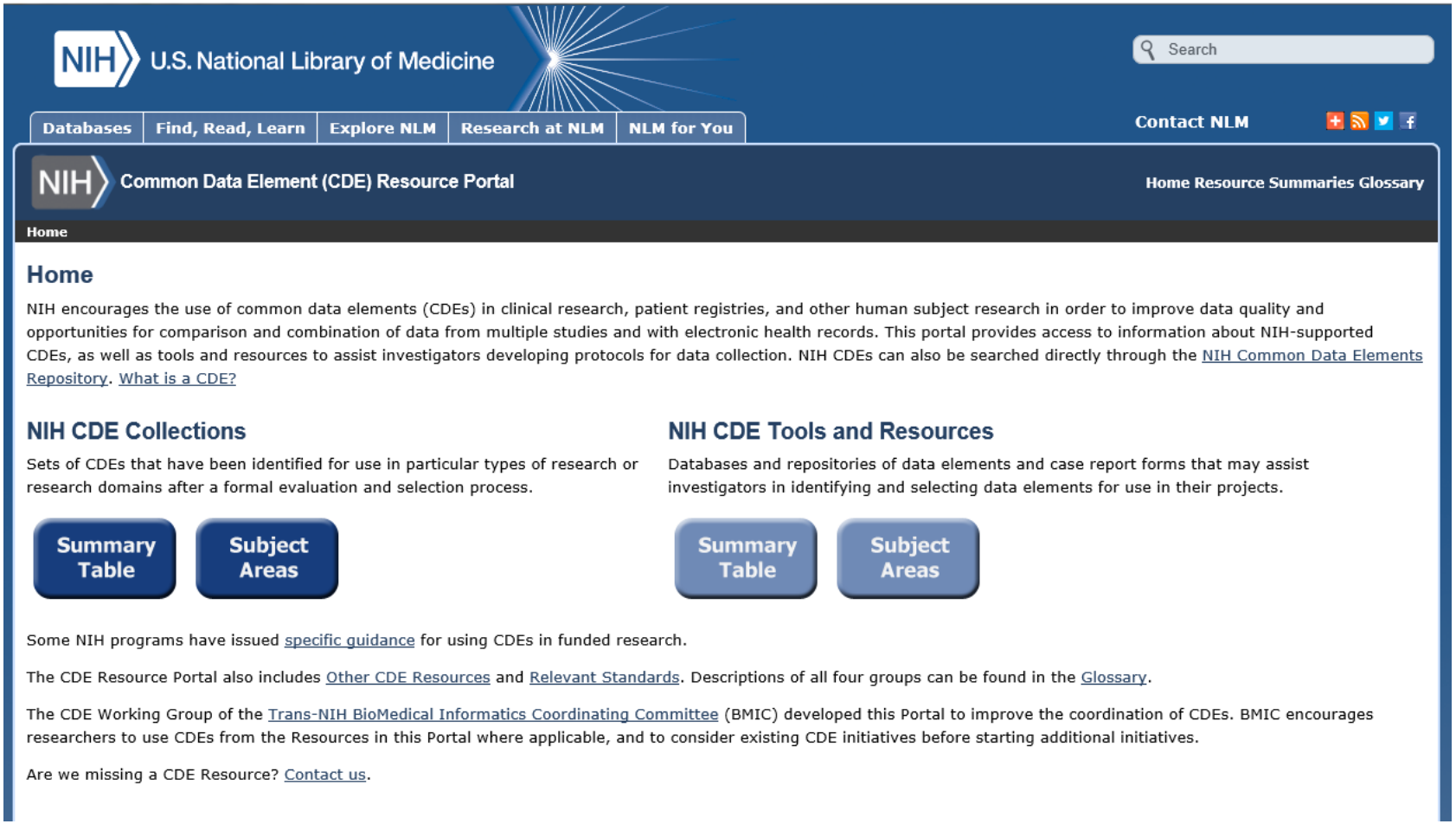
From: NCI Wiki – CTEP Common Data Elements.
https://wiki.nci.nih.gov/display/caDSR/CTEP+Common+Data+Elements

Clinical and research objectives for SUD CDEs

Emmes

- **Use of standardized data collection for SUD in clinical trials, registries, EHRs, and clinical decision support**
- **Use of standardized data in quality measures**
- **Facilitate the integration of SUD clinical research with data collection in general medical care (e.g., better support pragmatic trials, CER, registries, etc.)**
- **Interoperability for the exchange of data for data science initiatives**

CDEs at the NIH



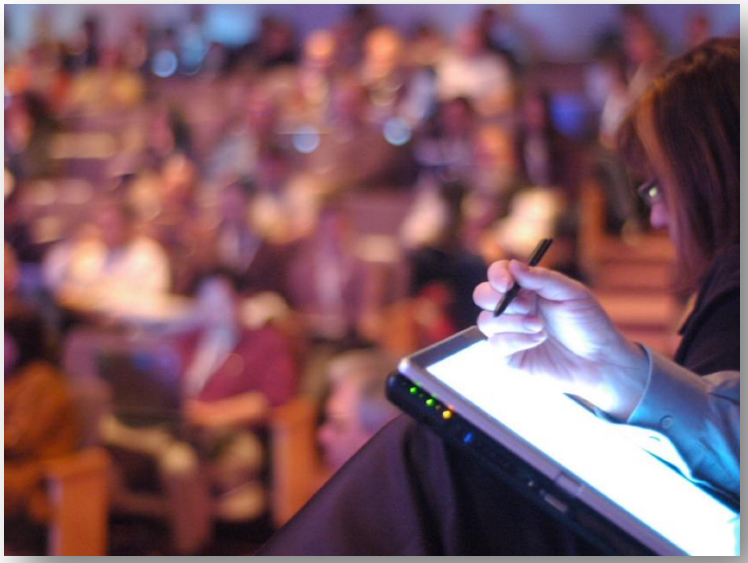
NIH CDE Initiatives

This table lists summary information for NIH CDE Initiatives. More information on NIH CDE Initiatives: Subject Areas, Detailed Summaries.

Show 50 entries Search:

Link to Homepage	Link to CDEs	Brief Summary	Subject Area	Number of Elements	CDE Resource Contact
Standardized Asthma Outcomes for Clinical Research	Asthma CDEs	The standardized asthma outcomes for clinical research represent recommendations for core (required in future studies), supplemental (to be used according to study aims), and emerging (requiring validation and standardization) outcomes for 7 domains of asthma clinical research outcome measures. More...	Asthma. More...	10 (adults), 25 (children)	NHLBI, NIAID
Chronic Low Back Pain CDEs	cLBP	Recommended minimum dataset for research on chronic low back pain. More...	Chronic low back pain. More...	40	NCCAM
Early Detection Research Program	EDRN	CDEs for use in describing samples and data collected as part of cancer biomarker research. More...	Cancer. More...	1,600	NCI
National Ophthalmic Disease Genotyping Network	eyeGENE	As part of eyeGENE, common data elements have been developed for collecting phenotypic data associated with more than 30 inherited ophthalmic diseases. More...	Ophthalmology. More...	300+	NEI
Global Rare Diseases Patient Registry and Data Repository	GRDR	CDEs to facilitate standardized data collection into the GRDR and to assist organizations in establishing rare disease registries that contribute information to GRDR. More...	Rare diseases. More...	70	ORDR
Quality of Life Outcomes in Neurological Disorders	Neuro-QOL	A core set of quality-of-life questions that address chronic neurologic disorders, plus sets of supplemental questions specific to targeted diseases or subgroups of patients. More...	Neurological disorders. More...	500	NINDS
NIDA Substance Abuse Electronic Health Record Data Elements	NIDA EHR	A set of brief screening and initial assessment tools for substance use disorders (SUDs) for use in general medical settings. More...	Substance Use Disorders. More...	80+	NIDA
NIH Toolbox for Assessment of Neurological and Behavioral Function	NIH Toolbox	An integrated set of tools for measuring cognitive, emotional, motor and sensory function. More...	Cognitive, emotional, motor, and sensory function. More...	4 batteries of tests, each with 5-24 tests	NIH
NINDS Common Data Elements	NINDS CDEs	A core set of data elements for use in NINDS-funded studies, including core and supplementary sets of data elements for use in disease-specific studies. More...	Neurological disorders. More...	10,000 unique variables, 550+ instruments	NINDS
Consensus Measures for Phenotypes and eXposures	PhenX	Standard measures related to complex diseases, phenotypic traits and environmental exposures for inclusion in genome-wide association studies (GWAS) and other large-scale genomic and epidemiologic research efforts. More...	Genome-wide association studies. More...	15,000+ variables, 428 protocols	NHGRI
Patient Reported Outcomes Measurement Information System	PROMIS	A system of item banks measuring patient-reported health status for various domains of physical, mental, and social health across clinical populations (i.e. not disease-specific). More...	Physical, mental, and social health. More...	50 item banks	NIAMS

Our process in developing CDEs for SUD - Expert Consultation & Consensus




NLM
OBSSR
NIH
CDC, IHS, VA
AAAP
ASAM
CPDD
SBM
APA
NASADAD
AHRQ
62 CTPs +
HCPs
ONDCP
CMS
SUD EHR
SAMHSA HRSA
NIDA CTN

Workshops/Symposia

- NIDA-sponsored 'Electronic Medical Records Workshop', Sept. 24, 2010
- NIH/OBSSR- and SBM-sponsored workshop 'Identifying Core Behavioral and Psychosocial Data Elements for the Electronic Health Record', May 2-3, 2011
- Other venues :
  - AAAP, 2010
  - ASAM, 2011
  - APA, 2011
  - INEBRIA, 2011; CPDD, 2011
  - ONC/SAMHSA Behavioral Health CQM TEP – Drug Use, 2012

Expert Key Recommendations

Emmes

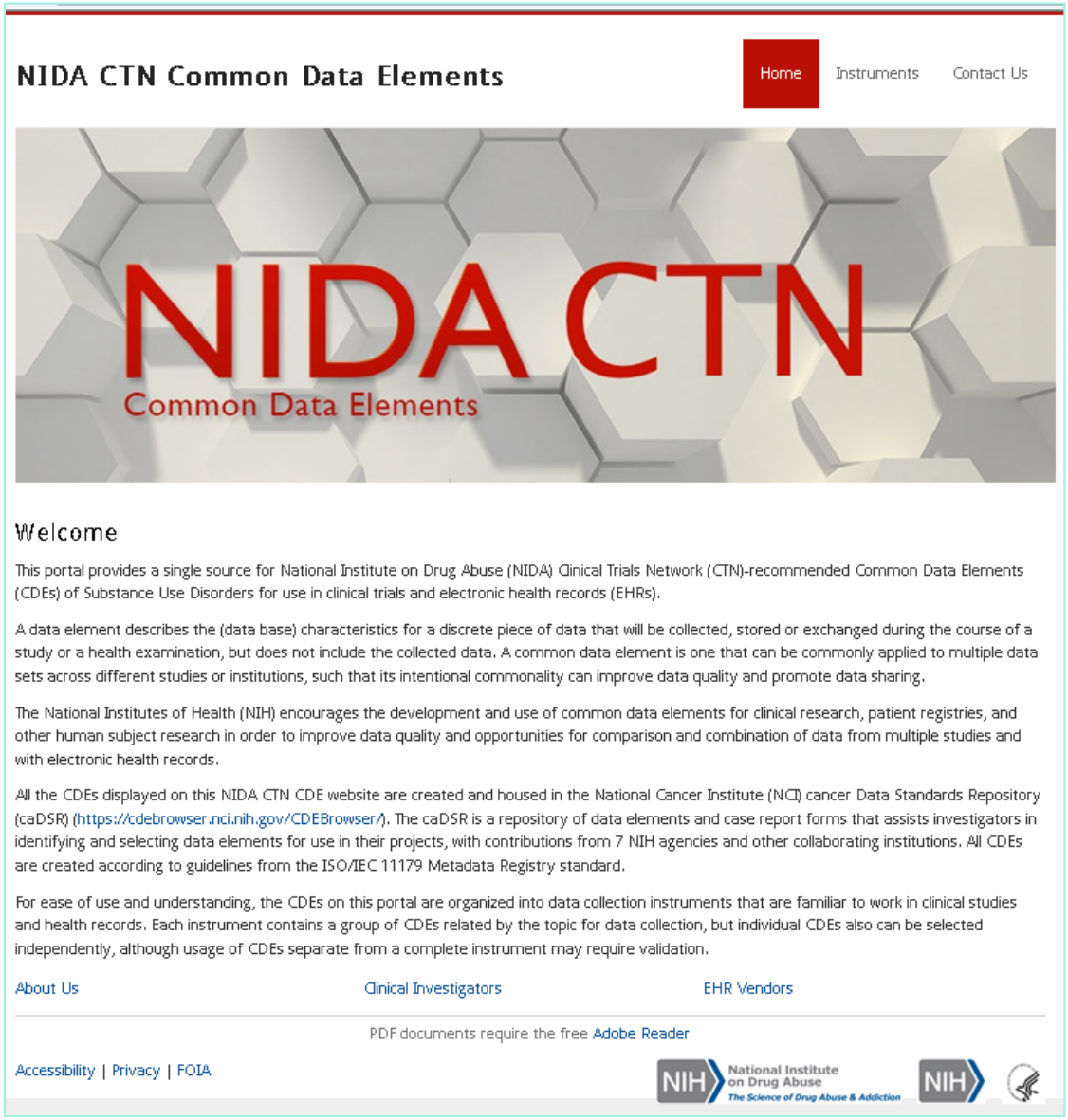
- Keep it brief for primary care
- Combine screening of tobacco, alcohol and substance use in primary care
- Use validated screening questions above all other considerations
- Develop longitudinal questions with a standardized timeframe
- Use standardized questions or instruments for additional assessments
- Incorporate clinical decisions and evidence-based brief interventions
- Consider ASAM dimensions and The Joint Commission (TJC) standards

Feedback from Primary Care Providers

- **Need single question screener**
- **Brief assessment (3 questions better than 10)**
- **Actual question does not matter as much as making a decision and moving forward**
- **For EHR development – questions and assessments be validated**

Disseminating NIDA CDEs

http://cde.drugabuse.gov/


NIDA CTN Common Data Elements
Home
Instruments
Contact Us
NIDA CTN
Common Data Elements
Welcome
This portal provides a single source for National Institute on Drug Abuse (NIDA) Clinical Trials Network (CTN)-recommended Common Data Elements (CDEs) of Substance Use Disorders for use in clinical trials and electronic health records (EHRs).
A data element describes the (data base) characteristics for a discrete piece of data that will be collected, stored or exchanged during the course of a study or a health examination, but does not include the collected data. A common data element is one that can be commonly applied to multiple data sets across different studies or institutions, such that its intentional commonality can improve data quality and promote data sharing.
The National Institutes of Health (NIH) encourages the development and use of common data elements for clinical research, patient registries, and other human subject research in order to improve data quality and opportunities for comparison and combination of data from multiple studies and with electronic health records.
All the CDEs displayed on this NIDA CTN CDE website are created and housed in the National Cancer Institute (NCI) cancer Data Standards Repository (caDSR) (https://cdebrowser.nci.nih.gov/CDEBrowser/). The caDSR is a repository of data elements and case report forms that assists investigators in identifying and selecting data elements for use in their projects, with contributions from 7 NIH agencies and other collaborating institutions. All CDEs are created according to guidelines from the ISO/IEC 11179 Metadata Registry standard.
For ease of use and understanding, the CDEs on this portal are organized into data collection instruments that are familiar to work in clinical studies and health records. Each instrument contains a group of CDEs related by the topic for data collection, but individual CDEs also can be selected independently, although usage of CDEs separate from a complete instrument may require validation.
About Us
Clinical Investigators
EHR Vendors
PDF documents require the free Adobe Reader
Accessibility | Privacy | FOIA
NIH National Institute on Drug Abuse
The Science of Drug Abuse & Addiction
NIH

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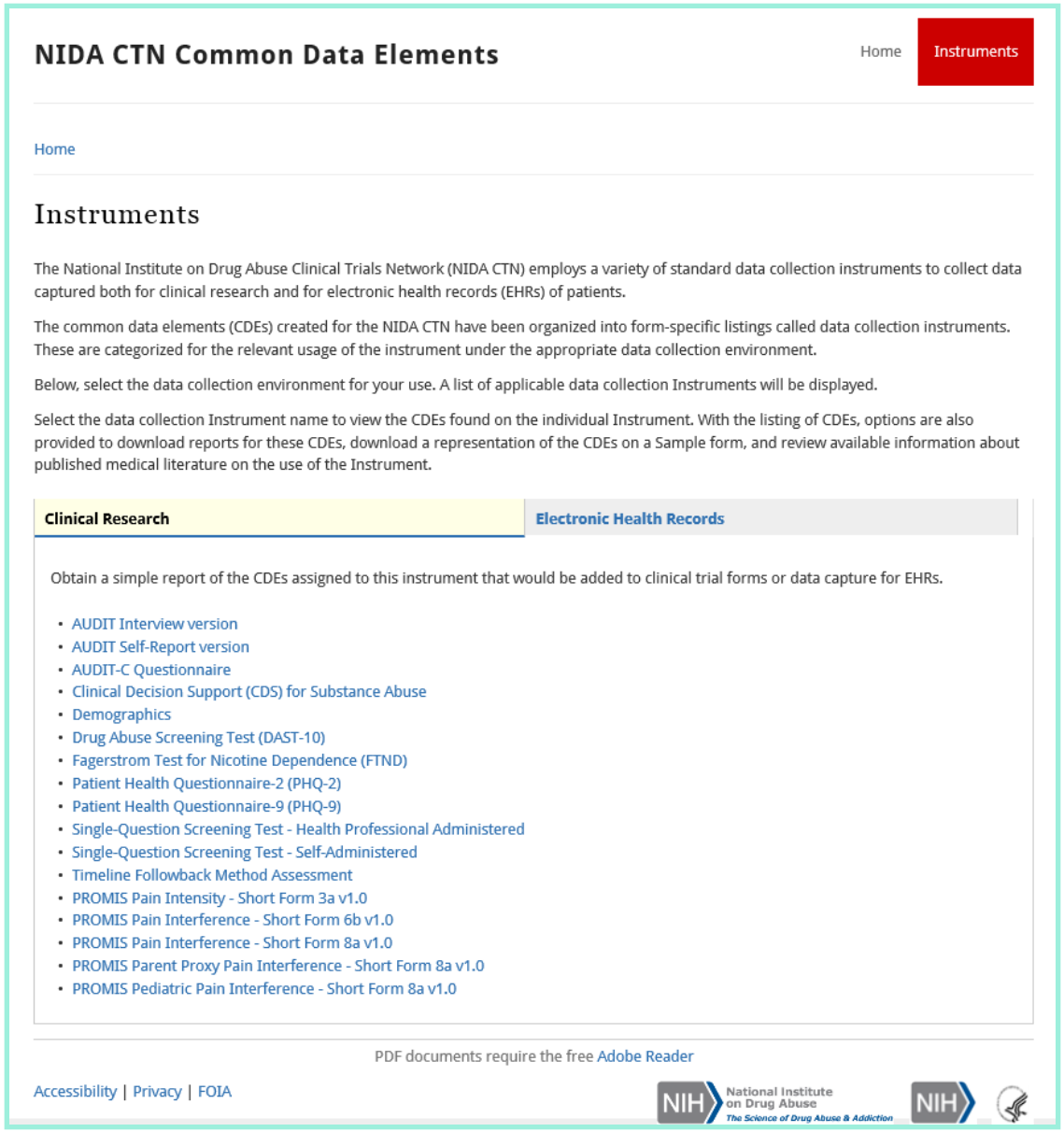

NIDA CTN Common Data Elements

Home | Instruments

Home

Instruments

The National Institute on Drug Abuse Clinical Trials Network (NIDA CTN) employs a variety of standard data collection instruments to collect data captured both for clinical research and for electronic health records (EHRs) of patients.

The common data elements (CDEs) created for the NIDA CTN have been organized into form-specific listings called data collection instruments. These are categorized for the relevant usage of the instrument under the appropriate data collection environment.

Below, select the data collection environment for your use. A list of applicable data collection Instruments will be displayed.

Select the data collection Instrument name to view the CDEs found on the individual Instrument. With the listing of CDEs, options are also provided to download reports for these CDEs, download a representation of the CDEs on a Sample form, and review available information about published medical literature on the use of the Instrument.

Clinical Research | Electronic Health Records

Obtain a simple report of the CDEs assigned to this instrument that would be added to clinical trial forms or data capture for EHRs.

- AUDIT Interview version
- AUDIT Self-Report version
- AUDIT-C Questionnaire
- Clinical Decision Support (CDS) for Substance Abuse
- Demographics
- Drug Abuse Screening Test (DAST-10)
- Fagerstrom Test for Nicotine Dependence (FTND)
- Patient Health Questionnaire-2 (PHQ-2)
- Patient Health Questionnaire-9 (PHQ-9)
- Single-Question Screening Test - Health Professional Administered
- Single-Question Screening Test - Self-Administered
- Timeline Followback Method Assessment
- PROMIS Pain Intensity - Short Form 3a v1.0
- PROMIS Pain Interference - Short Form 6b v1.0
- PROMIS Pain Interference - Short Form 8a v1.0
- PROMIS Parent Proxy Pain Interference - Short Form 8a v1.0
- PROMIS Pediatric Pain Interference - Short Form 8a v1.0

PDF documents require the free Adobe Reader

Accessibility | Privacy | FOIA

NIH National Institute on Drug Abuse The Science of Drug Abuse & Addiction

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Clinical Research | **Electronic Health Records**

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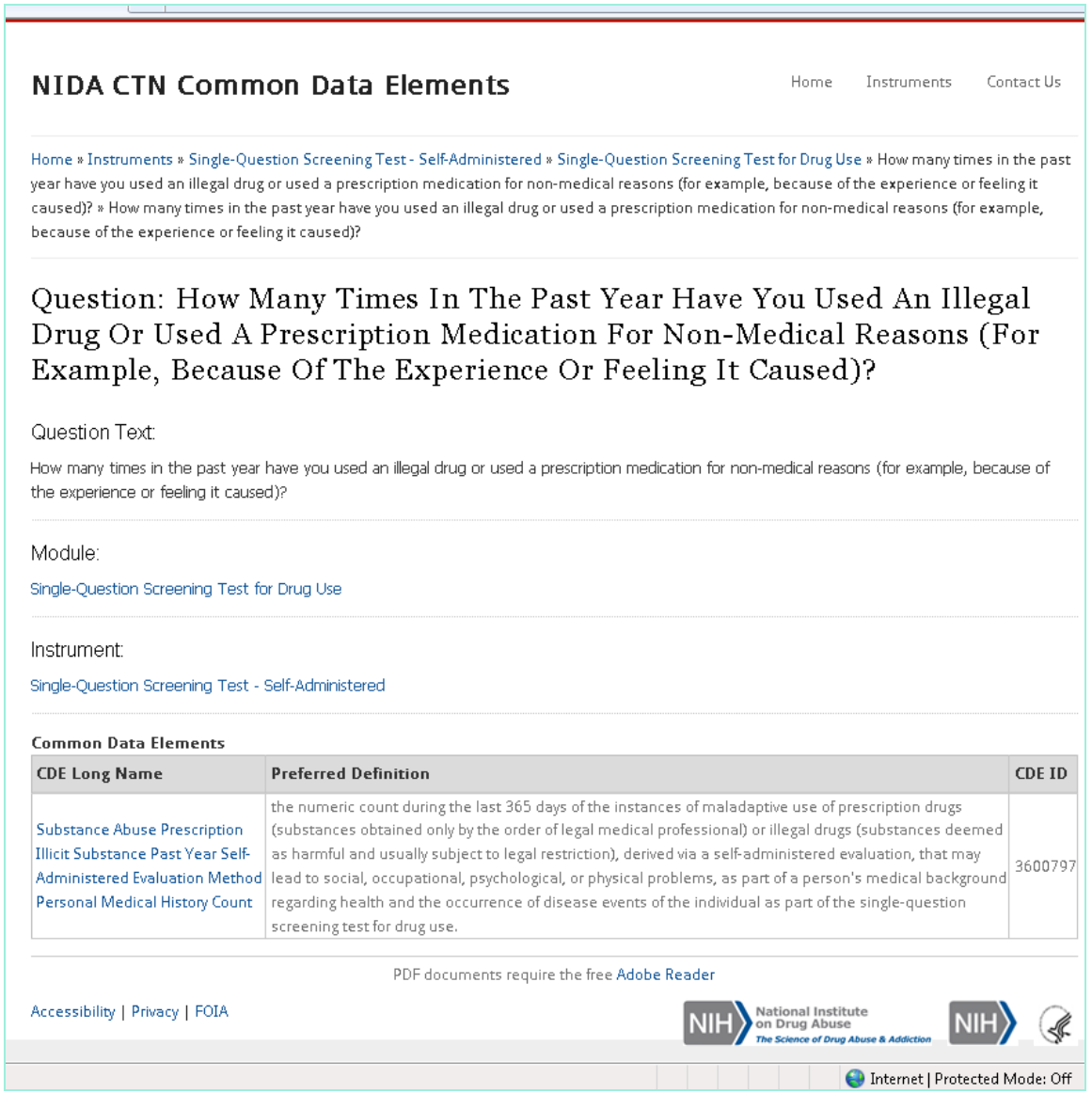

NIDA CTN Common Data Elements

Home Instruments Contact Us

Home » Instruments » Single-Question Screening Test - Self-Administered » Single-Question Screening Test for Drug Use » How many times in the past year have you used an illegal drug or used a prescription medication for non-medical reasons (for example, because of the experience or feeling it caused)? » How many times in the past year have you used an illegal drug or used a prescription medication for non-medical reasons (for example, because of the experience or feeling it caused)?

Question: How Many Times In The Past Year Have You Used An Illegal Drug Or Used A Prescription Medication For Non-Medical Reasons (For Example, Because Of The Experience Or Feeling It Caused)?

Question Text:

How many times in the past year have you used an illegal drug or used a prescription medication for non-medical reasons (for example, because of the experience or feeling it caused)?

Module:

Single-Question Screening Test for Drug Use

Instrument:

Single-Question Screening Test - Self-Administered

Common Data Elements

CDE Long Name	Preferred Definition	CDE ID
Substance Abuse Prescription Illicit Substance Past Year Self-Administered Evaluation Method Personal Medical History Count	the numeric count during the last 365 days of the instances of maladaptive use of prescription drugs (substances obtained only by the order of legal medical professional) or illegal drugs (substances deemed as harmful and usually subject to legal restriction), derived via a self-administered evaluation, that may lead to social, occupational, psychological, or physical problems, as part of a person's medical background regarding health and the occurrence of disease events of the individual as part of the single-question screening test for drug use.	3600797

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NIH National Institute on Drug Abuse The Science of Drug Abuse & Addiction NIH

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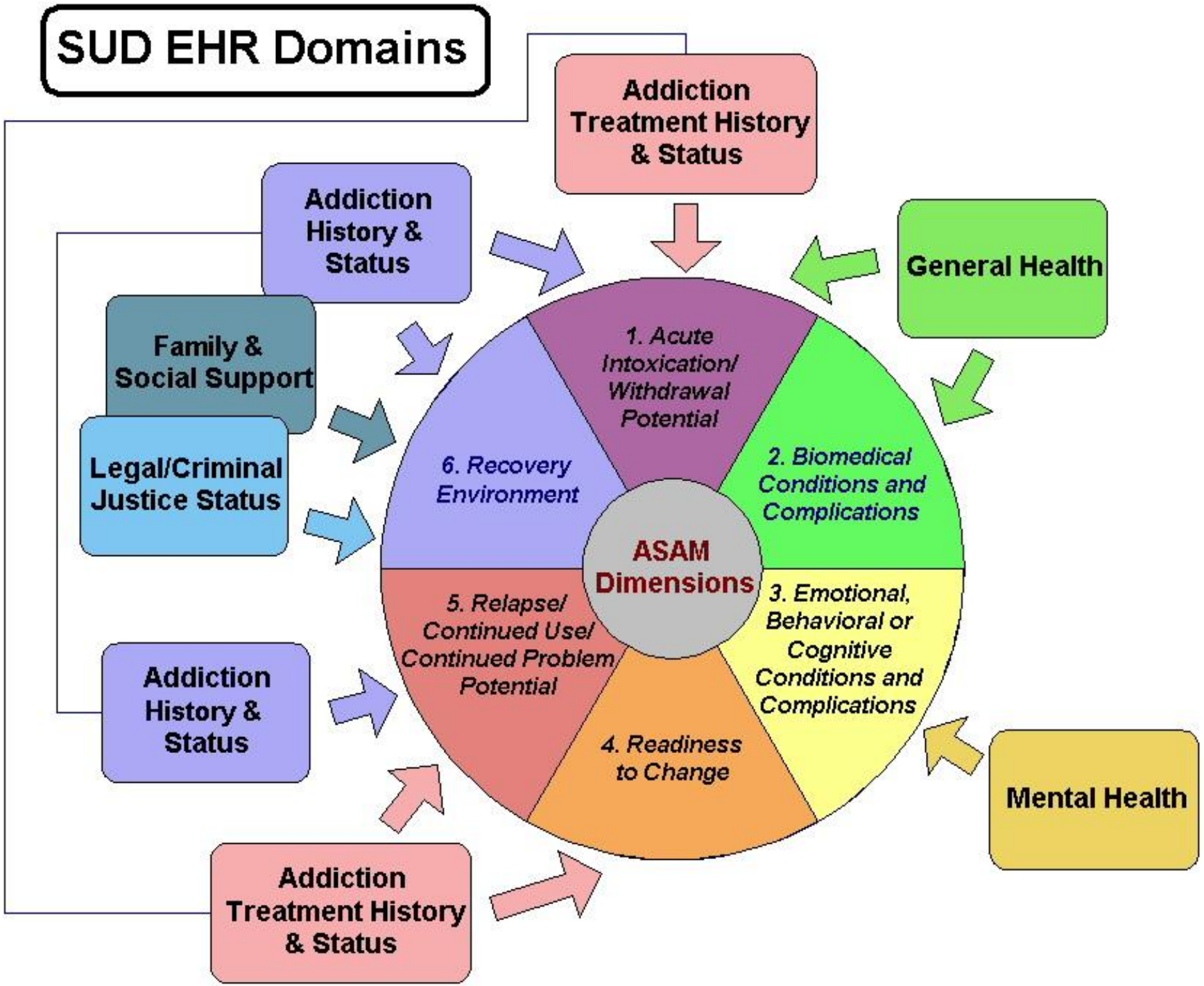
SUD EHR Domains
Addiction Treatment History & Status
Addiction History & Status
General Health
Family & Social Support
Legal/Criminal Justice Status
1. Acute Intoxication/ Withdrawal Potential
2. Biomedical Conditions and Complications
6. Recovery Environment
ASAM Dimensions
3. Emotional, Behavioral or Cognitive Conditions and Complications
5. Relapse/ Continued Use/ Continued Problem Potential
4. Readiness to Change
Addiction History & Status
Mental Health
Addiction Treatment History & Status

Clinical Decision Support

- NIDA Clinical Decision Support Expert Consensus Meeting, July 13, 2011 organized by Dr. Geetha Subramanian (NIDA CTN)
- Feedback on CDS also sought at:
  - INEBRIA, 2011
  - CPDD, 2012

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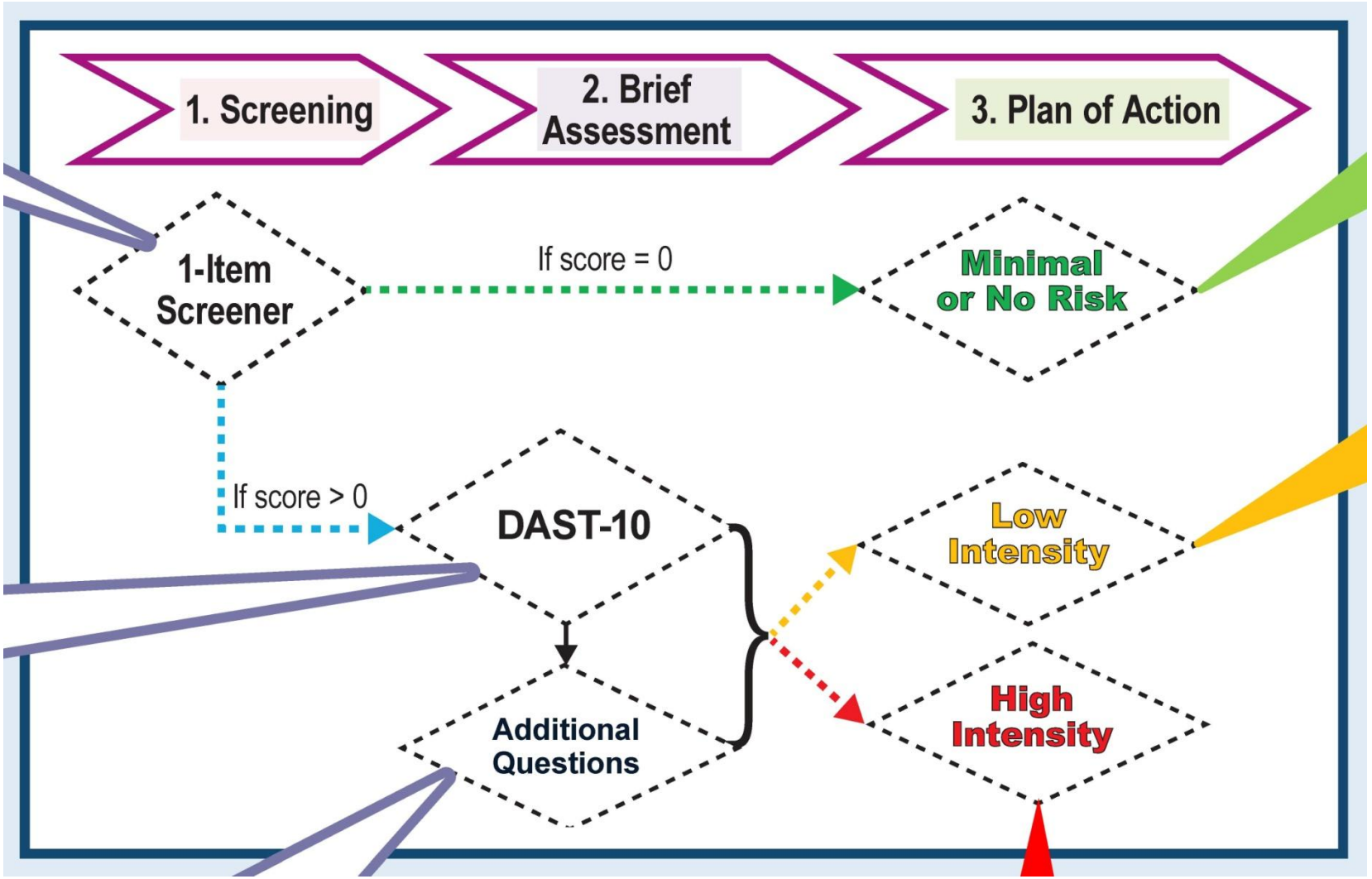
Clinical Decision Support



Emmes

High Intensity Intervention (Level Red)

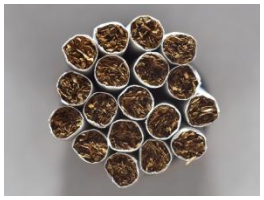
Screening Criteria	**DAST-10 only**	DAST-10 scores > 3 (equal to or greater than 3)
	OR	
	DAST-10 Score	0–2
	AND	• Daily use of any substance • Weekly use of opioids, cocaine, or stimulants • Injection drug use in the past three months • Currently in drug abuse treatment
	Additional Criteria	
Actions to Consider	• **Recommend cessation** • Assess **readiness to change** • Facilitate **referral** to an addiction specialist/program for further assessment/treatment • Encourage **mutual help group meeting attendance** • **Additional issues** to consider: o Review current medications o Obtain drug abuse treatment history o Order urine drug screen o Obtain tobacco and alcohol use history o Screen for common mental health conditions o Provide preventive health screening (e.g., HIV) o Refer for **immediate crisis interventions**, if needed o Schedule **1 month follow-up visit** **For patients with opioid dependence:** • Initiate on-site/integrated **medication-assisted treatment** for opioid dependence **or** • **Refer to an outside provider**/organization for medication-assisted treatment	

NIDA/ASAM Composite eClinical Quality Measure

- Recommendation of the ONC-SAMHSA Behavioral health CQM Technical Expert Panel, August 9, 2012

"Percentage of patients aged 18 years and older who were screened at least once within the last 24 months for tobacco use, unhealthy alcohol use, nonmedical prescription drug use, and illicit drug use AND who received an intervention for all positive screening results"

- Incorporates NQF-endorsed AMA/PCPI component measures for alcohol and tobacco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Behavioral health integration under the ACA

Emmes

- **Definition[1]:**

"whole person care that focuses on overall health; creates partnerships across all aspects of health; and is facilitated by a variety of clinical, structural, and financial arrangements and community supports that remove barriers between physical and behavioral healthcare"

1. Croze, C. for the Association for Behavioral Health and Wellness (ABWH), 2015. Healthcare Integration in the Era of the Affordable Care Act.

Role of EHRs and CDEs in behavioral health care integration

Emmes

- **EHRs that cross boundaries of individual organizations working to provided integrated care and eventually of multiple health networks leading to a Nationwide network**
- **Within this integrated clinical care environment, further integration of clinical care and clinical research will foster the IOM's vision**
- **CDEs provide the semantic interoperability that is one part of the ability to broadly share meaningful data for clinical research**

National Institute on Drug Abuse
The Science of Drug Abuse & Addiction

Clinical Trials Network (CTN)

- Law/Policy (ACA 2010, CHIPRA 2009, MHPAEA 2008)
- Regulatory
- Ethics
- Methodology

Informed Decision Making

Informed Decision Making

CMS Medicaid/FQHC

CMS MUC — In progress

Composite illegal/Rx drug, alcohol and tobacco eCQM — In progress

Evidence Gatekeepers: USPSTF, CMS, NQF, AHRQ

Process Enablers

Integrated SUD in PC

- PCMH guided by CCM, Medicaid, SUD comorbidities

Clinical Research Data

Research Implementation

Clinical Implementation

Clinical Care Data

- New RCTs
- Registries
- CER, PCOR
- 2nd ary use/re-use of health data

Evidence-based Clinical Care

Technical Enablers

Standard Instruments: SSI, DAST-10, AUDIT, FTND

SUD EHR, SBI, CDS & digital/smart tools — Developed & In progress

CTN CDE Website — In progress

NIH BD2K objectives

ONC/HITECH Standards & eSpecification:
- SNOMED
- LOINC, etc.

EMR/EHR Vendors

CTN Investigators

Ongoing

Selected References on EHRs

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- Tai, B. Sparenborg, S et al. Expanding the National Drug Abuse Treatment Clinical Trials network to address the management of substance use disorders in general medical settings. ***Journal of Substance Abuse Treatment*** 2014 5:75-80. doi: 10.2147/SAR.S66538

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NIDA References on CDEs

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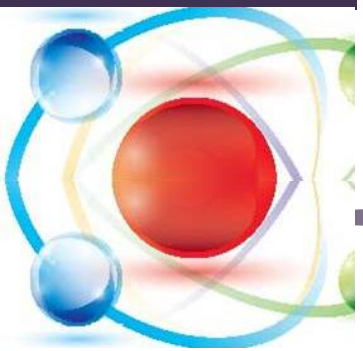

THANK YOU FOR YOUR PARTICIPATION