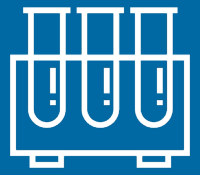
COVID-19 Lab Working Group

Data Innovations

Topics



I. COVID-19 Knowledge Updates

II. COVID-19 Use Cases for EP Evaluator

III. Instrument Manager Driver Updates

IV. Support Services for COVID-19

V. Q&A

COVID-19 Resources from Data Innovations

- COVID-19 Driver Listing
- News Blog
- Recurring webinar series

Upcoming Webinars

COVID-19 Lab Working Group

Wed., May 27th

10:00 AM PT/ 1:00 PM ET

New Release Update: IM 2020 Edition, Version 8.17

Wed., June 3rd

10:00 AM PT /1:00 PM ET

COVID-19 News Summary

Current and Future Laboratory Impacts/Considerations

Data Innovations

Topics

I. COVID-19 Testing and Reimbursement
II. Future COVID-19 Considerations
III. Resources

COVID-19 Testing and Reimbursement

Testing decision-making and economic impact

Based on clinical need and demand

Decision-making

Sensitivity and specificity

Reimbursement

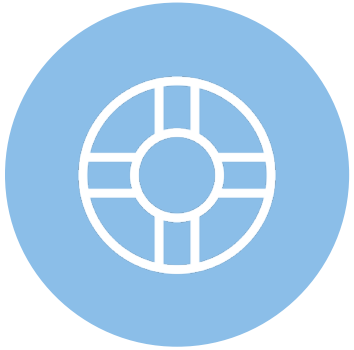
Decision made

What does the future hold for COVID-19 testing?

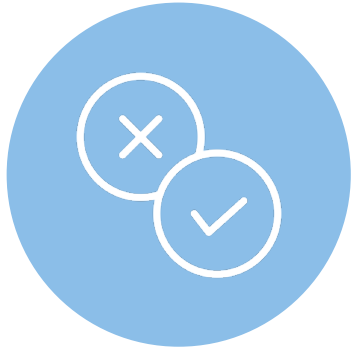
Future COVID-19 Considerations

Watch for changes in incident rates

Watch for changes in FDA approval



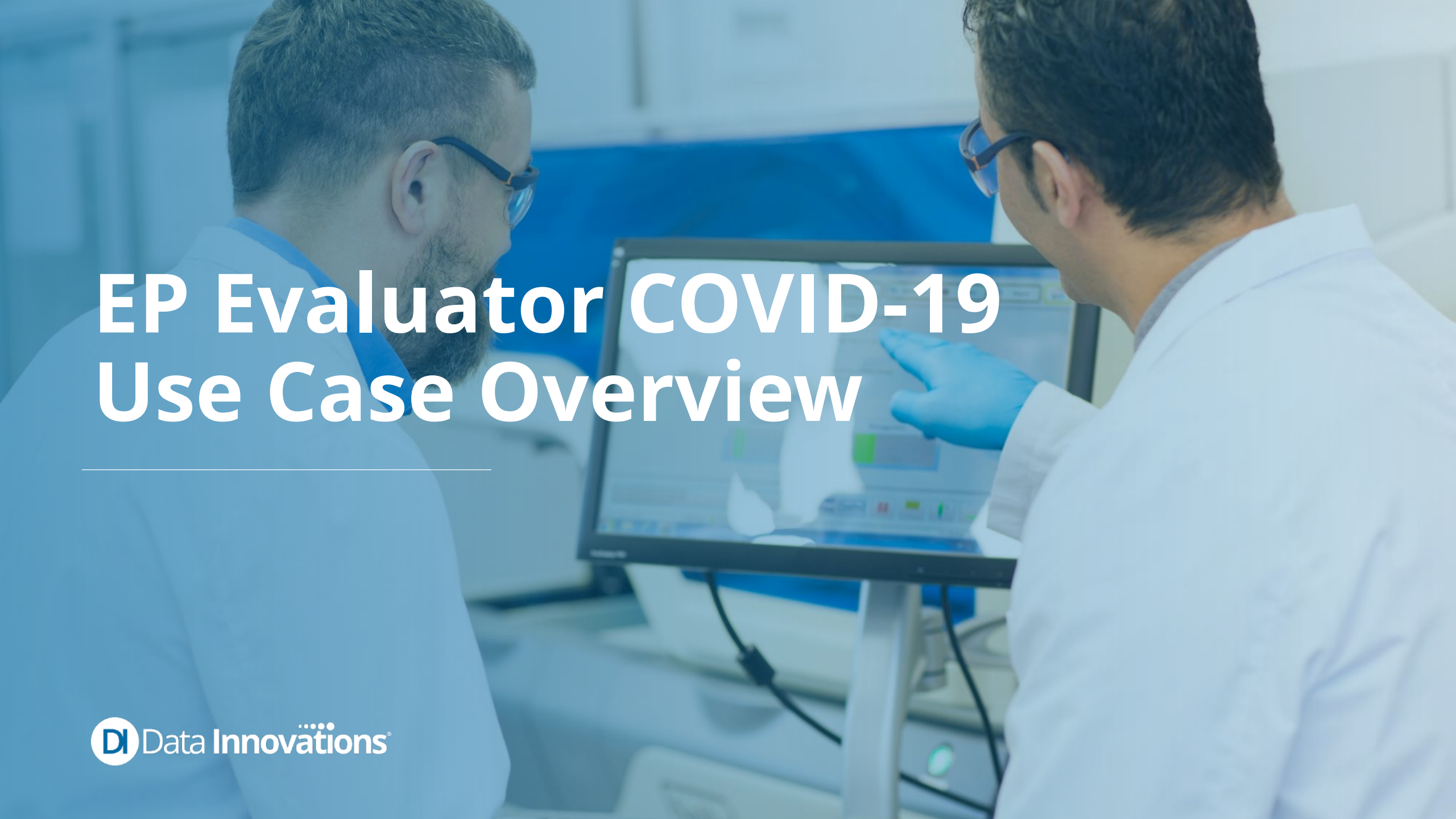
Will the lab be thrown a lifeline? $$$



Critically analyze challenges and successes

Useful links & webinars

- 360dx.com
- Darkdaily.com
- Others



EP Evaluator COVID-19 Use Case Overview

Data Innovations

Lab Quality Assurance with EP Evaluator

- Accelerate the Performance Verification (PV) studies
- Improve the accuracy of instrument PV studies
- Industry leader in streamlining performance validation
- Compliant, inspector-ready reports

Instrument and method validation at scale

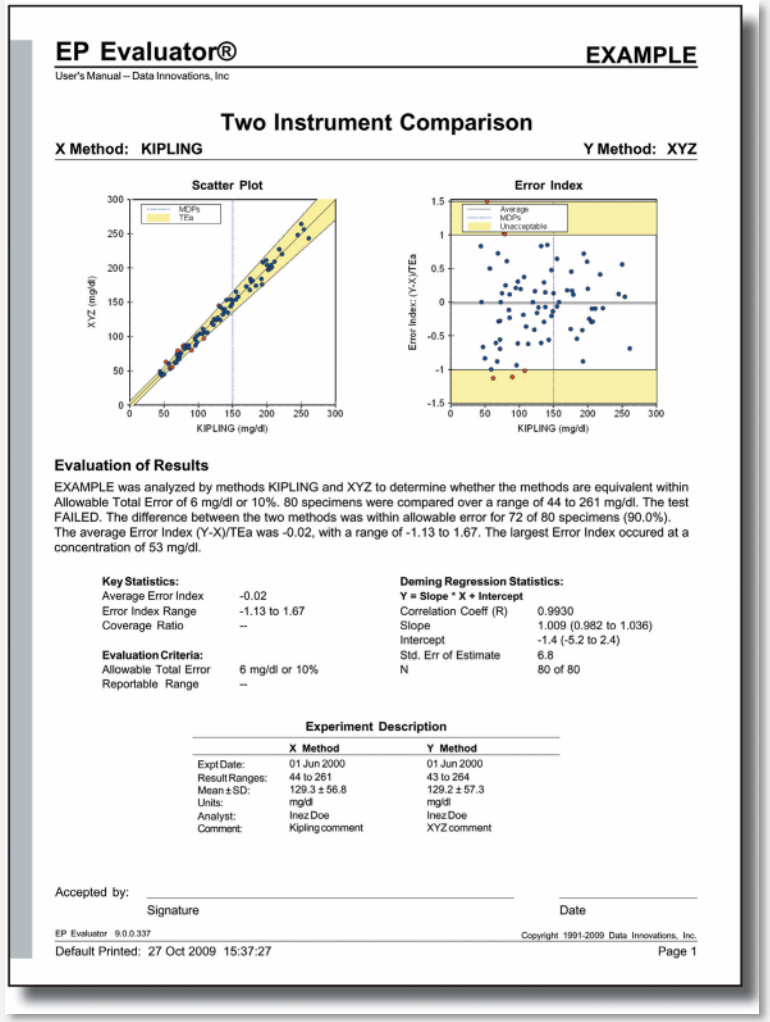
Perform calculations for 100+ experiments simultaneously

Simplify instrument-to-instrument comparison

Conduct multiple instrument comparisons

Validate according to your lab's specific ranges

Instant, easy-to-read, inspector-ready reports



EP Evaluator® EXAMPLE

User's Manual -- Data Innovations, Inc

Two Instrument Comparison

X Method: KIPLING **Y Method: XYZ**

Scatter Plot

Error Index

Evaluation of Results

EXAMPLE was analyzed by methods KIPLING and XYZ to determine whether the methods are equivalent within Allowable Total Error of 6 mg/dl or 10%. 80 specimens were compared over a range of 44 to 261 mg/dl. The test FAILED. The difference between the two methods was within allowable error for 72 of 80 specimens (90.0%). The average Error Index (Y-X)/TEa was -0.02, with a range of -1.13 to 1.67. The largest Error Index occured at a concentration of 53 mg/dl.

Key Statistics:	
Average Error Index	-0.02
Error Index Range	-1.13 to 1.67
Coverage Ratio	--
Evaluation Criteria:	
Allowable Total Error	6 mg/dl or 10%
Reportable Range	--

Deming Regression Statistics: Y = Slope * X + Intercept	
Correlation Coeff (R)	0.9930
Slope	1.009 (0.982 to 1.036)
Intercept	-1.4 (-5.2 to 2.4)
Std. Err of Estimate	6.8
N	80 of 80

Experiment Description

	X Method	Y Method
Expt Date:	01 Jun 2000	01 Jun 2000
Result Ranges:	44 to 261	43 to 264
Mean ± SD:	129.3 ± 56.8	129.2 ± 57.3
Units:	mg/dl	mg/dl
Analyst:	Inez Doe	Inez Doe
Comment:	Kipling comment	XYZ comment

Accepted by: _____ _____

Signature Date

EP Evaluator 9.0.0.337 Copyright 1991-2009 Data Innovations, Inc.

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- Rapid
- High-throughput
- Easy-to-read, printable reports
- Regulation compliant with CLIA, The CAP, The Joint Commission, and COFRAC requirements

Current environment and how EP Evaluator can help

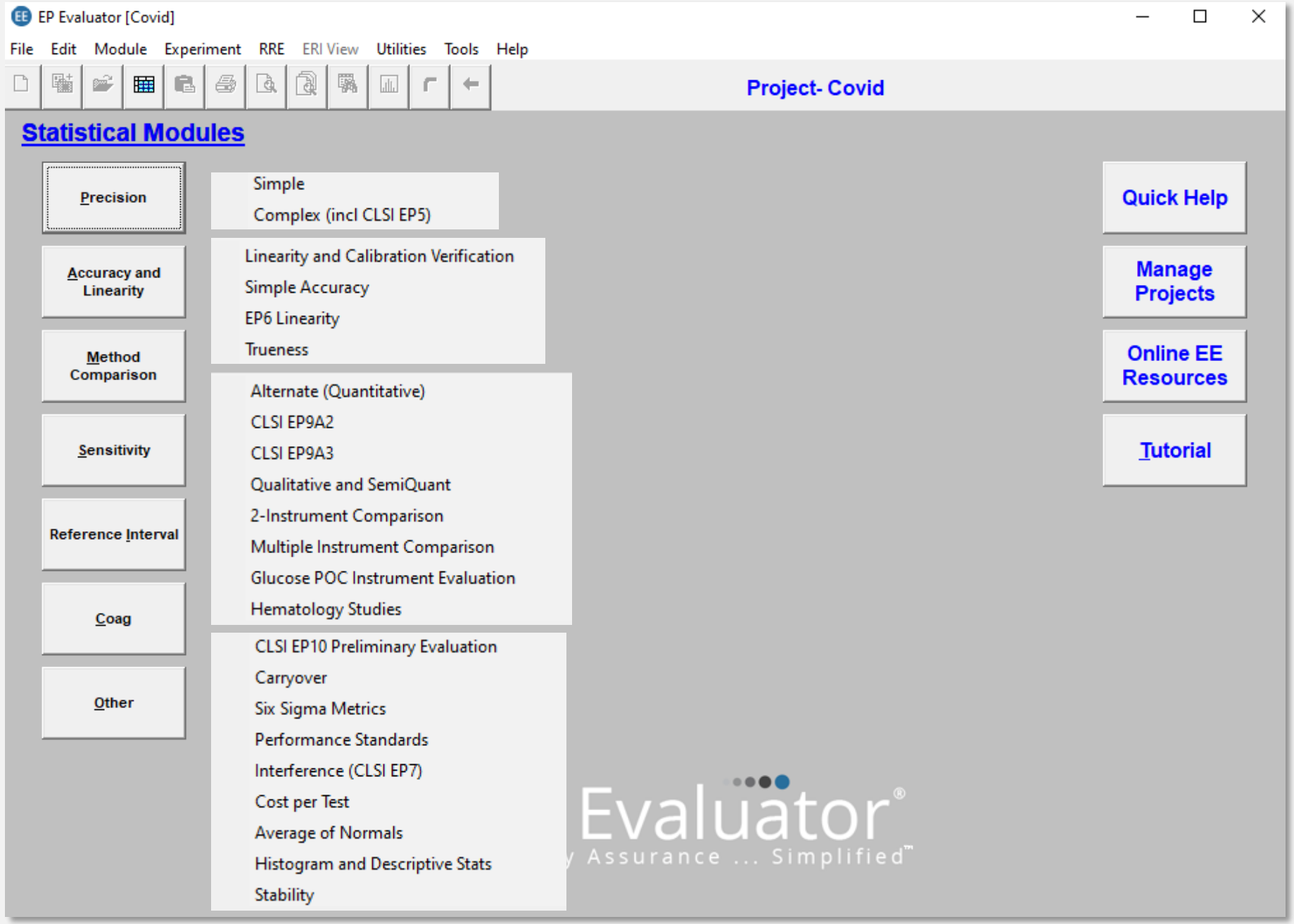
1. Comparing performance between Laboratory Developed Assays and Manufacturer provided assays on one or more platforms
2. Onboarding a new assay on an existing platform or go-live on new instrument
3. Running periodic Performance Verification studies to meet CLIA or The CAP requirements
4. Trying to create laboratory developed assays under the FDA-Emergency Use Authorization (EUA)

Use Cases: Comparing LDTs vs Comm Tests, Onboarding New Assays, Running PVs

Statistical Modules	EP Module	Short Description
Precision	SP	Simple Precision experiments evaluate the degree to which repeated measurements of the same specimen (or specimens) show the same result. To do this statistically it calculates mean, SD, and CV.
Linearity	Linearity and Cal Verification	
Method Comparison	Alternate (Quantitative)	Basic correlation
	QMC	Concordance-Compares results from qualitative or semi-quantitative methods.

Use Case: Creating an LDT

CLSI /EP Guideline	EP Module	Short Description
EP 5	CP - Complex Precision	CP calculates within run, between run, between day, and total precision. The CLSI EP5 protocol is a subset of this statistical module.
EP 6	EP6 - Linearity	This module verifies linearity.
EP 7	EP7-Interference	Interference estimates the maximum level of an interferent that can be present without causing a clinically significant change in the analyte measurement.
EP 9	EP9 A2 - Method Comparison	EP9A2 (based on CLSI EP09-A2) EP9A2 is a statistically rigorous method comparison protocol that requires a minimum of 39 specimens assayed in duplicate.
	EP9 A23 - Method Comparison	EP9A3 (based on CLSI EP09-A3) The EP9A3 module is a new advanced method comparison module designed for use with the CLSI protocol document.
EP10	CLSI EP10 Preliminary Evaluation	This module is a fast, simple, protocol to do a preliminary evaluation of a new method for linearity, recovery, precision, carryover, and drift.
(12)	QMC	Compares results from qualitative or semi-quantitative methods.
(17)	LOQ	Sensitivity determines the lowest concentration that can be measured with acceptable precision.
(28)	VRI	Verification of Reference Interval (VRI) uses a minimum of twenty values to verify a previously established reference interval.
	ERI/ROC	(ERI) establishes a new reference interval
(21)	6SIG	provides guidelines for setting an Allowable Total Error goal.
(25)	STB EP25	evaluates rate of measurand drift.
(15)	SP	Simple Precision experiments evaluate the degree to which repeated measurements of the same specimen (or specimens) show the same result. To do this statistically it calculates mean, SD, and CV.


EP Evaluator [Covid]
File
Edit
Module
Experiment
RRE
ERI View
Utilities
Tools
Help
Project- Covid
Statistical Modules
Precision
Accuracy and Linearity
Method Comparison
Sensitivity
Reference Interval
Coag
Other
Simple
Complex (incl CLSI EP5)
Linearity and Calibration Verification
Simple Accuracy
EP6 Linearity
Trueness
Alternate (Quantitative)
CLSI EP9A2
CLSI EP9A3
Qualitative and SemiQuant
2-Instrument Comparison
Multiple Instrument Comparison
Glucose POC Instrument Evaluation
Hematology Studies
CLSI EP10 Preliminary Evaluation
Carryover
Six Sigma Metrics
Performance Standards
Interference (CLSI EP7)
Cost per Test
Average of Normals
Histogram and Descriptive Stats
Stability
Quick Help
Manage Projects
Online EE Resources
Tutorial
Evaluator®
Assurance ... Simplified™

Ease-of-use

Data Entry Type	Considerations	EP Evaluator Product Type	Grade
Manual entry	Slow speed of entry, typos, one analyte at a time	All	Good
Rapid keyboard entry from instrument printouts using a panel defined worksheet	Rapid Results Entry (RRE)	Standard	Good
Copy-and-paste from Microsoft Excel	RRE Wizard for multiple analytes, multiple instruments – but still need to put the data into the worksheet	Standard	Better
Instrument data capture – RRE Wizard	Cable hookup, or instrument generated file. Drivers for IVD manufacturers only	Pro	Better
Data capture from Instrument Manager	RRE – Simple data query for thousands of results	Pro	Best

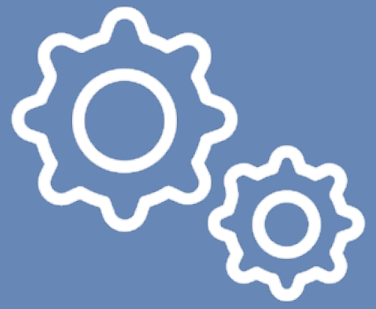
Resources

- https://www.datainnovations.com/ep-evaluator-resources
- https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations
- https://clsi.org/standards-development/helpful-documents-for-covid-19-testing/

Driver Update

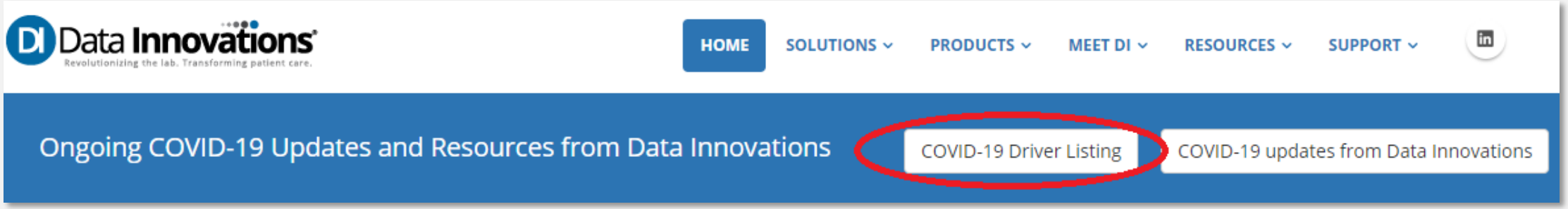
Data Innovations

Evaluating Drivers



- Driver requests associated with COVID-19 testing are given the highest priority
- Beta testing will be available to any sites willing to test

COVID-19 Driver Listing



- Driver Listing can be accessed by button on website homepage
- Current list has 45+ drivers for devices associated with COVID-19 testing

Customer Support

Data Innovations

Topics

I. Customer Support response to COVID-19
II. How to get help from Data Innovations
III. How to download a driver

Customer Support (CS) COVID-19 Protocol

We strive to continue to use common sense, empathy, and flexibility to help support our customers

Considered high priority

Applies to all products on and off hours

Process for assistance to other departments accelerated

CS is working closely with Development, InterSystems, Training, and Professional Services

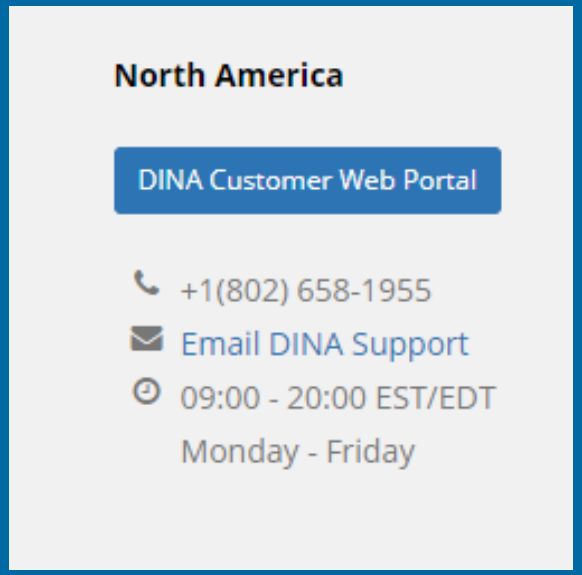
Need help? Contact us!

- Provide a clear description of issue to ensure expedited resolution
- Direct phone response from support team to capture complete ticket info

Questions to anticipate

- Is this COVID-19 related?
- Description of the issue or problem
  - Copy/paste error into the description
- Is this a live production system? Did this ever function as expected?
- What has changed?
- What troubleshooting has already occurred, if any?
- License # of affected Instrument Manager software
- If connection or instrument/LIS specific:
  - What is the instrument/LIS?
  - What driver & driver version is being used?
- Contact name, #, email of person to contact to begin troubleshooting.
- If you have data, let us know.

A few key considerations



- Escalation procedures vary from site-to-site
  - Are you to work directly with Data Innovations or through a Business Partner?
- Know where your Instrument Manager server is physically located and who can access it
- Know your IM license number for quicker identification of your site

Downloading a Driver

Click here to see the screen capture video

Lab Q&A

Lab Q&A

Samantha K. Miller, MPA, MLS (ASCP)CM
LIS Analyst

- Hurley Medical Center, Flint, MI

Dr. Samuel Reichberg, Associate Medical Director

- Northwell Health Laboratories, New York, NY

Questions?

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www.datainnovations.com

Need help? Contact us.

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Monday - Friday

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Monday - Friday

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DIEMEA Customer Web Portal

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UK: (+44) (330) 808 0025
France: (+33) (1) 76 63 74 20
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Monday - Friday

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09:00 to 18:00 HKT
Monday - Friday