



# MDIC-FDA Workshop: Advancing EUA IVD Products Toward Full Marketing Status

February 3, 2020 – Supplemental Information

## Articles:

Durski K, Singaravelu S, Teo J, Naidoo D, Bawo L, Jambai A, Keita S, Yahaya A, Muraguri B, Ahounou B, et al. 2017. **Development, Use, and Impact of a Global Laboratory Database During the 2014 Ebola Outbreak in West Africa.** The Journal of Infectious Diseases, 2017;215:1799-806.

Gliklich RE, Leavy M. **Assessing Real-World Data Quality. The application of patient registry quality criteria to real-world data and real-world evidence.** Ther Innov Regul Sci, March, 2019.

Gliklich RE, Dreyer NA, Leavy M. **Registries for Evaluating Patient Outcomes: A User's Guide 3rd edition.** Rockville (MD): Agency for Healthcare Research and Quality (US); 2014 Apr. Report No. 13(14)-EHC111.

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Lurie N, Manolio T, Patterson A, Collins F, Friedman T. 2013. **Research as a Part of Public Health Emergency Response.** N Engl J Med 2013; 368:1251-1255 DOI:10.1056/NEJMs1209510

Petway M, Anderson L, Humes R, Sincock S, Kuhnert-Tallman W, Miller J, Wallace R. 2019. **Implementation of the US Department of Health and Human Services Zika Specimen Repository and Its Effect on Zika Diagnostic Test Development.** Public Health Reports, 2019, Vol. 134(Supplement 2) 53S-57S.

Pollock NR, Wonderly B. 2017. **Evaluating novel diagnostics in an outbreak setting: lessons learned from Ebola.** J Clin Microbiol 55:1255-1261. <https://doi.org/10.1128/JCM.00053-17>

Tembo J, Simulundu E, Changula K, Handley D, Gilbert M, Chilufya M, Asogun D, Ansumana R, Kapata N, Ntoumi F, et al. 2019. **Recent advances in the development and evaluation of molecular diagnostics for Ebola virus disease.** Expert Review of Molecular Diagnostics, 19:4, 325-340, DOI:10.1080/14737159.2019.1595592

**Can Digital Health Help Stop the Next Epidemic?** [https://www.csis.org/analysis/can-digital-health-help-stop-next-epidemic?utm\\_source=CSIS+All&utm\\_campaign=a8e101b535-EMAIL\\_CAMPAIGN\\_2019\\_02\\_04\\_09\\_42\\_COPY\\_01&utm\\_medium=email&utm\\_term=0\\_f326fc46b6-a8e101b535-222420929](https://www.csis.org/analysis/can-digital-health-help-stop-next-epidemic?utm_source=CSIS+All&utm_campaign=a8e101b535-EMAIL_CAMPAIGN_2019_02_04_09_42_COPY_01&utm_medium=email&utm_term=0_f326fc46b6-a8e101b535-222420929)

**Why the huge surge in EEE cases? Federal rules requiring quick sample disposal mean we may never know.** <https://www.statnews.com/2019/11/27/surge-eee-cases-federal-rules-requiring-quick-sample-disposal/>

## Web Links:

<https://www.finddx.org/pan-prep/>

<https://www.cdc.gov/pregnancy/zika/research/technical-clinical.html>

<https://www.who.int/topics/emergencies/en/>

[https://www.who.int/diagnostics\\_laboratory/eual/emergency/en/](https://www.who.int/diagnostics_laboratory/eual/emergency/en/)