

# **Implementation of NGS for Foodborne and Environmental Isolates in FDA ORA ORS Laboratories**

2018 GenomeTrakr Meeting  
September 27, 2018

# GenomeTrakr- Distribution

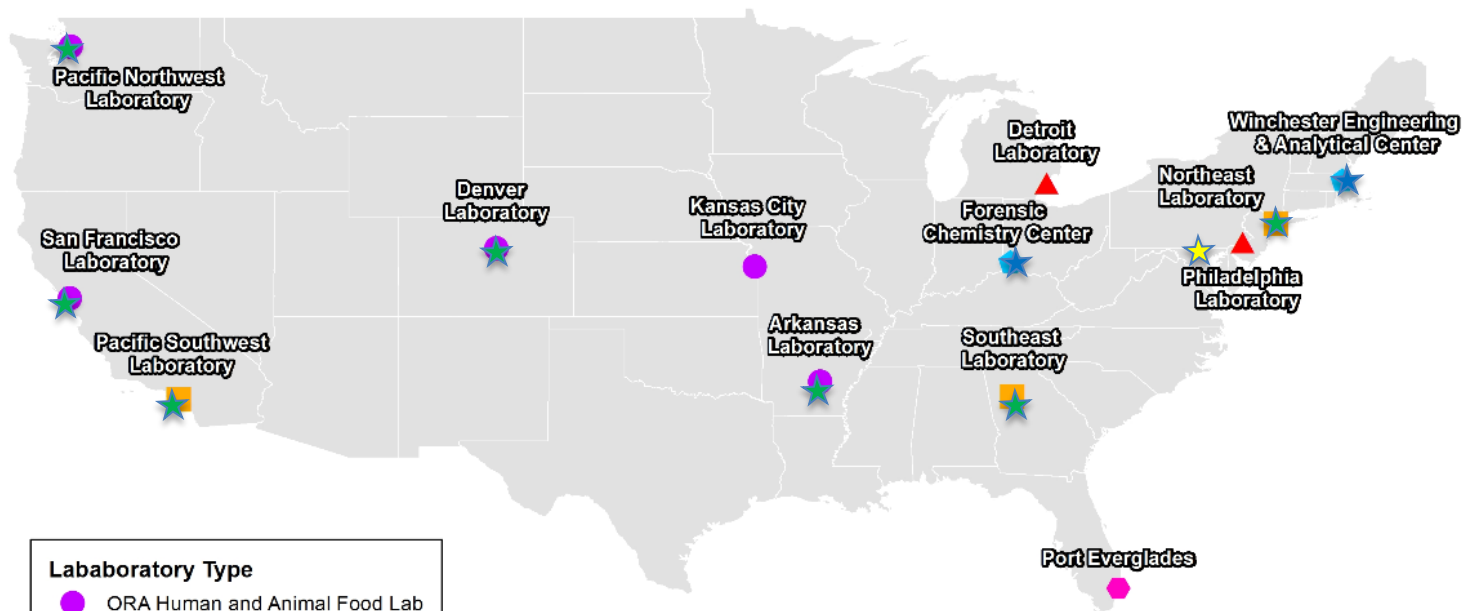
- Global Scale –
  - GenomeTrakr- Distributed network of labs producing WGS data
  
- FDA Scale –
  - Contributions to GenomeTrakr are also distributed
    - Center for Food Safety and Applied Nutrition (CFSAN)
      - GenomeTrakr – Genomics Coordination, Statistics/Bioinformatics, Research and Technical Consultation
    - Center for Veterinary Medicine (CVM)
      - National Antimicrobial Resistance Monitoring System (NARMS) –Implementation of ResistomeTracker
    - Office of Regulatory Affairs (ORA)
      - Regulatory food, animal feed and environmental sample collection and analysis
      - Repository of archive and real-time isolates
      - Confirm and subtype foodborne pathogens including by WGS
      - Research, PT and QAQC activities



# ORA ORS Laboratory GenomeTrakr Distribution

**ORA Laboratory Locations  
Office of Regulatory Science (ORS)**

**FDA U.S. FOOD & DRUG  
ADMINISTRATION**  
OFFICE OF REGULATORY AFFAIRS



**Laboratory Type**

- ORA Human and Animal Food Lab
- ▲ ORA Medical Products Lab
- ORA HAF & MPT (co-located)
- ◆ ORA Specialty Lab
- ORA Screening Station
- ▭ State Boundaries

- ★ HAF Lab - GenomeTrakr
- ★ MPTSL Lab - GenomeTrakr
- ★ ORS Scientific Program WGS Coordination

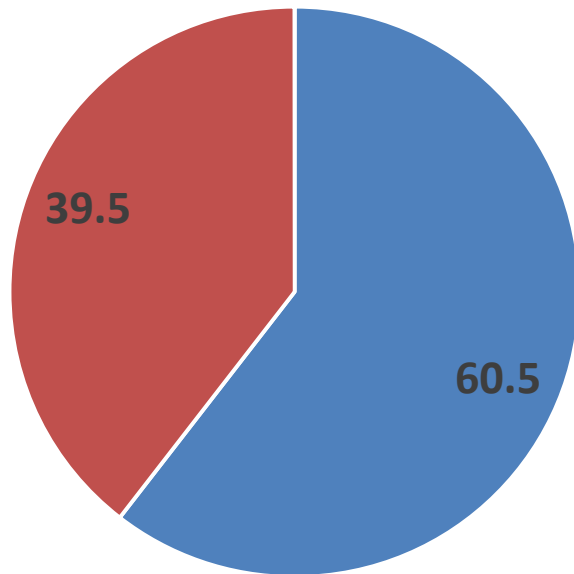
**San Juan  
Laboratory**

Puerto Rico - SJN

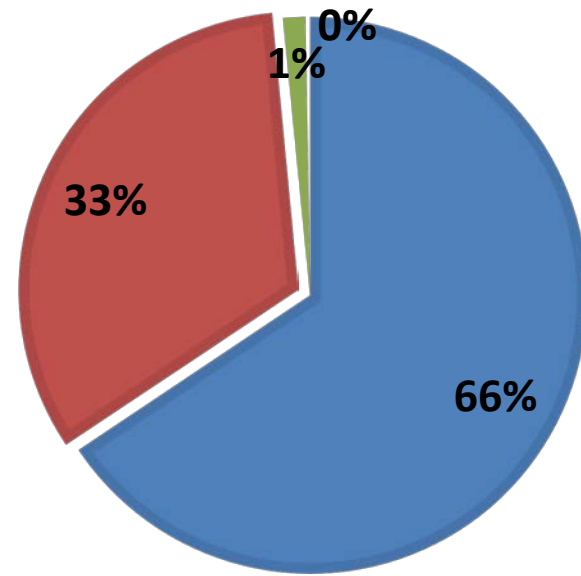
# WGS Implementation in ORA Timeline

- 2012 – Initial MiSeq instruments arrive (9 ORA labs)
- 2013 – Complete installation, training, begin sequencing archive collections (2000-2013)
- 2014 – ORA labs begin real-time WGS analysis of new isolates and continue with archive collections (2014-present)
- 2018 – 11541 sequences submitted to GenomeTrakr  
(2014-2018 average 2268 isolates/yr)  
OFFLO 7 Labs – Each equipped with 2 MiSeqs and QiaCube  
MPTSLO 1 Lab – 1 MiSeq and QiaCube

# Isolate Categories



■ Archives : ■ Real-time:



■ Salmonella ■ Listeria ■ E. coli ■ Other

\* Compiled from 09-04-2018 ORA Isolate Report

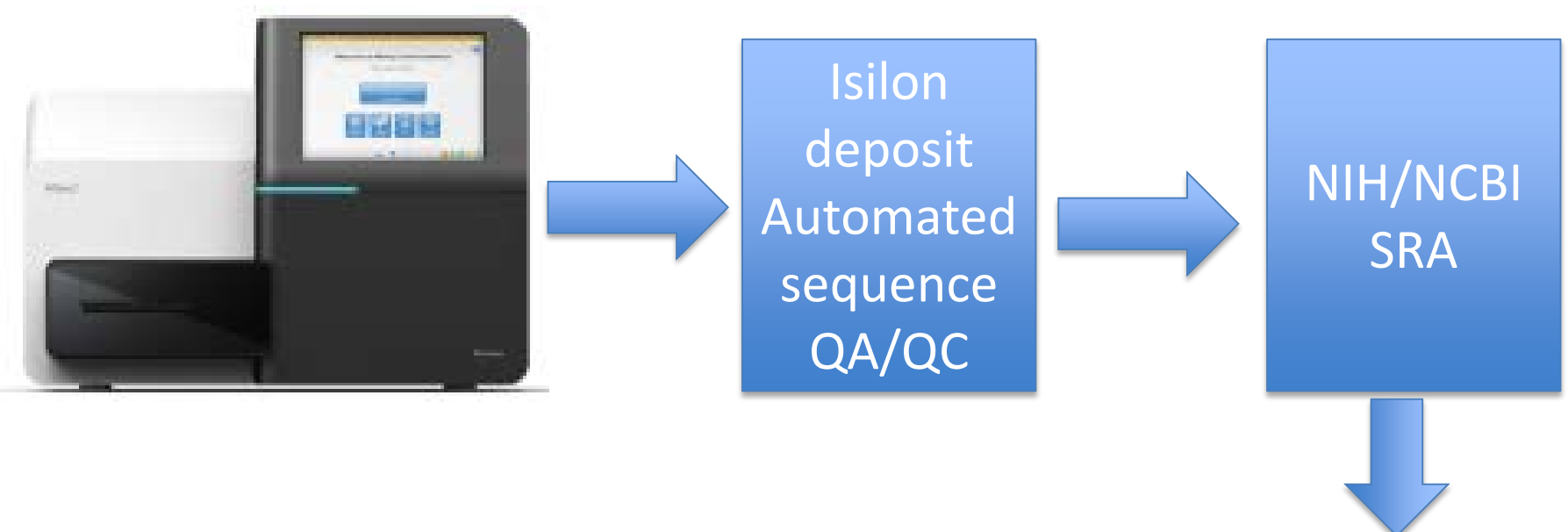
# Meta-Data Management

- FDA Sample Collection and Laboratory Analysis reports
  - Isolate number based on sample/sub or composite/pick
  - Genus /species/serotype
  - Collection date – sample collection
  - Collection source – detailed description
  - Location – Country and state
- GenomeTrakr – meta data registration
  - FDA Accession #
- ORA Labs and Isolate Status Reports
  - BioSample # and SRR #
  - Sequence QA/QC data
- NCBI Isolate Browser/Pathogen Detector/Rapid Reports
  - SNP Cluster
  - N50/Length/Contigs
- PulseNet Cluster Reports
  - Cluster or Outbreak codes

## Meta-Data Harmonization Workgroup

Evaluating the use of ORADDS reports to query and pull data from different sources in custom reports

# GenomeTrakr –Post Analytical



U.S. National Library of Medicine  
National Center for Biotechnology Information

Health > Pathogen Detection

## Pathogen Detection BLTA

**View the recent webinar: "Introducing the Pathogen Detection Isolates Browser"**

NCBI Pathogen Detection integrates bacterial pathogen genomic sequences originating in food, environmental sources, and patients. It quickly clusters and identifies related sequences to uncover potential food contamination sources, helping public health scientists investigate foodborne disease outbreaks.

[Find Isolates now!](#)

**Examples:**

- Search for isolates encoding a mobile colicin-variant gene and a KPC beta-lactamase  
`search[AMR_colicinvariant;AMR_KPC_beta_lactamase]`
- Search for *Salmonella* isolates from the USA  
`search[gen_loc_narr:USA AND taxname:Salmonella enterica]`

### Explore the Data

Species	New Isolates	Total Isolates
<i>Salmonella enterica</i>	30	117,150
<i>E.coli</i> and <i>Shigella</i>	152	32,688

**Learn More**

- About
- FAQ
- Browser: FactSheet
- [Antimicrobial Resistance FactSheet](#)
- [Antimicrobial Resistance](#)
- Cont/Status

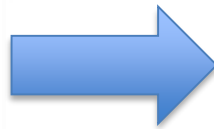
**Data Resources**

- [Isolates Browser](#)
- [Antimicrobial resistance reference gene database](#)
- [Isolates with antibiotic resistant phenotypes](#)
- [Beta lactamase resources](#)
- [Download analysis results \(FTP\)](#)

**Submit**

[How to submit data](#)

# Local- Post Analytical

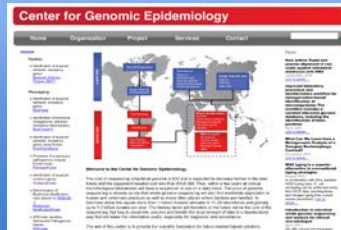


WGS Analysis  
Molecular Serotype  
Virulence Profile  
Phylogeny  
Assembly  
QA/QC

Center for Genetic Epidemiology

<http://www.genomicepidemiology.org/>

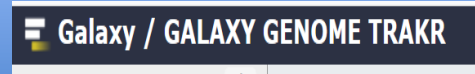
SeqSero  
SerotypeFinder  
VirulenceFinder  
Spades



GalaxyTrakr

<https://galaxytrakr.org/>

SeqSero / SISTR  
Ectyper  
FASTQC  
Spades



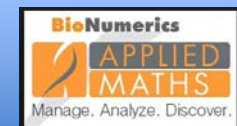
CLC Genomics Workbench

Assembly  
Sequence QC



BioNumerics ver 7.6

PulseNet QA/QC  
wgMLST



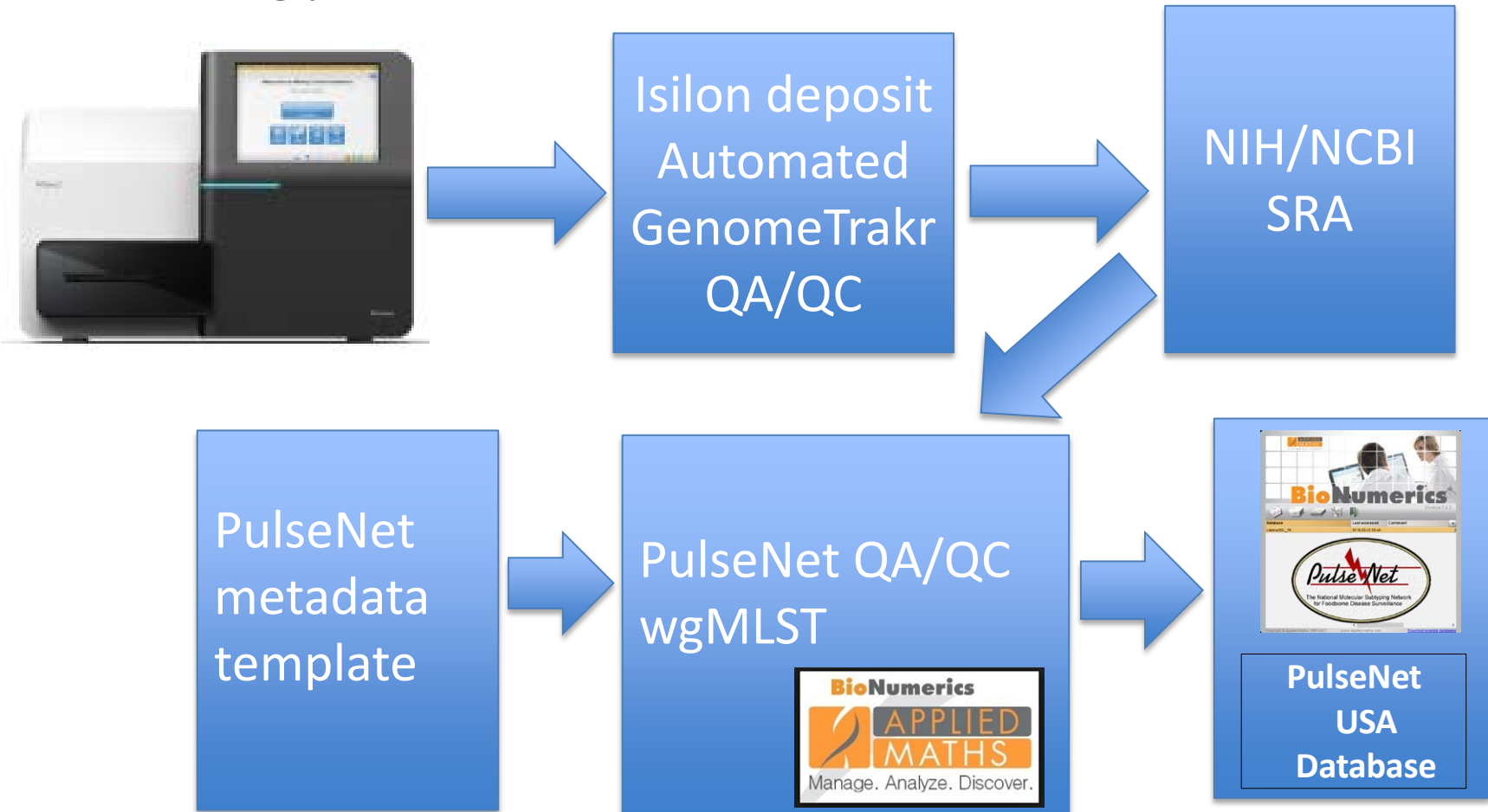


# PulseNet Participation

ORA ORS OFFLO PulseNet Labs: FNE/FSE/FAR/FDN/FSE/FSF/FNW

PFGE certified since 1999

Starting process WGS Certification



# Acknowledgements

- ORA/ORS WGS Teams
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  - David Melka



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