# The GenomeTrakr Experience

FDA U.S. FOOD & DRUG

**CENTER FOR FOOD SAFETY & APPLIED NUTRITION** 

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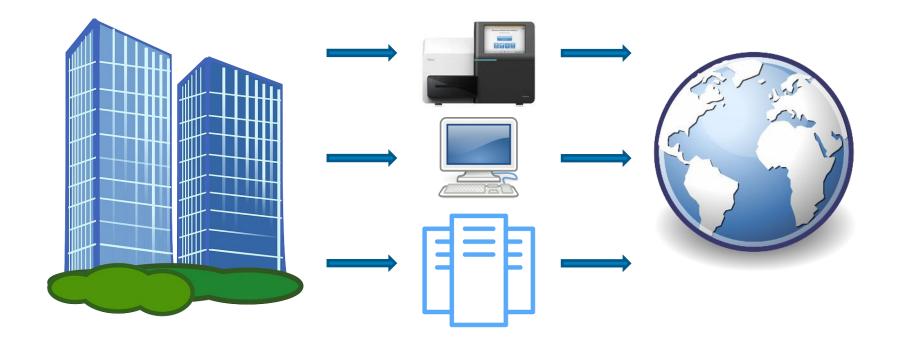


### The Past: PFGE surveillance and Private databases



### Transition Challenges: Infrastructure

- How is data trafficked in and out of your lab?
- Where is the data stored?
- How is the data analyzed/compared to other data?

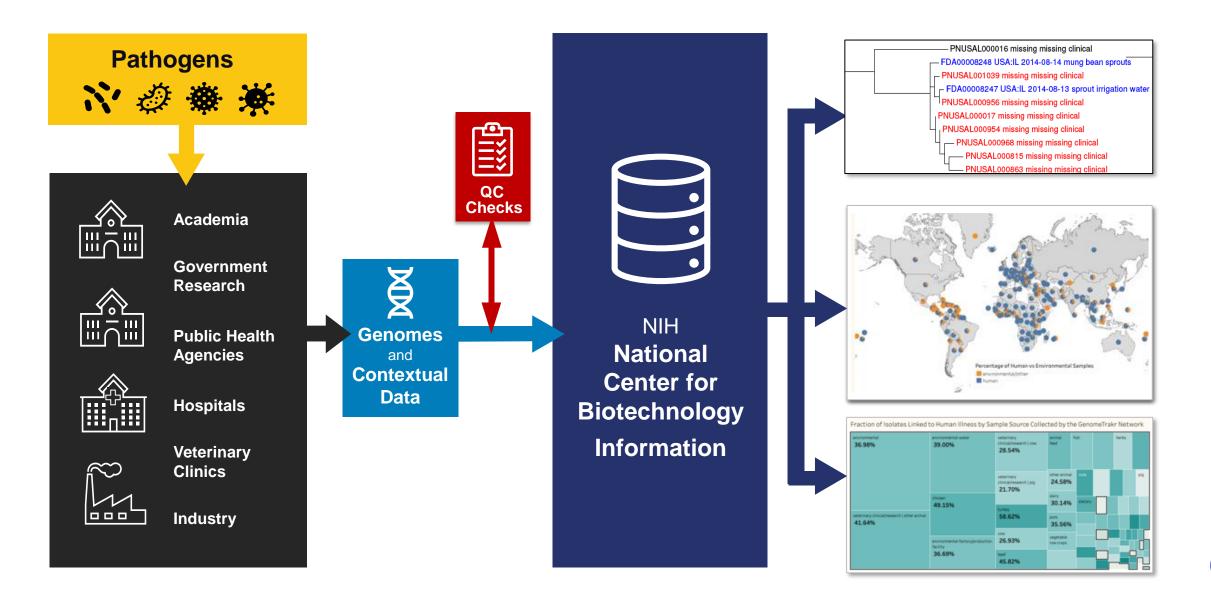




### The Present: Open Databases enable real-time linkages

### GenomeTrakr: Big Data





### **Best Practices:**

#### **BMC** Part of Springer Nature

#### One Health Outlook

Home About Articles Submission Guidelines

#### Review Open Access Published: 19 October 2020

Optimizing open data to support one health: best practices to ensure interoperability of genomic data from bacterial pathogens

Ruth E. Timme ⊠, William J. Wolfgang, Maria Balkey, Sai Laxmi Gubbala Venkata, Robyn Randolph, Marc Allard & Errol Strain

<u>One Health Outlook</u> 2, Article number: 20 (2020) | <u>Cite this article</u> 2353 Accesses | 11 Citations | 35 Altmetric | <u>Metrics</u>

#### Abstract

The holistic approach of One Health, which sees human, animal, plant, and environmental health as a unit, rather than discrete parts, requires not only interdisciplinary cooperation, but standardized methods for communicating and archiving data, enabling participants to easily share what they have learned and allow others to build upon their findings. Ongoing work by NCBI and the GenomeTrakr project illustrates how open data platforms can help meet the needs of federal and state regulators, public health laboratories, departments of agriculture, and universities. Here we describe how microbial pathogen surveillance can be transformed by having an open access database along with Best Practices for contributors to follow. First, we describe the open pathogen surveillance framework, hosted on the NCBI platform. We cover the current community standards for WGS quality, provide an SOP for assessing your own sequence quality and recommend QC thresholds for all submitters to follow. We then provide an overview of NCBI data submission along with step by step details. And finally, we provide curation guidance and an SOP for keeping your public data current within the database. These Best Practices can be models for other open data projects, thereby advancing the One Health goals of Findable, Accessible, Interoperable and Re-usable (FAIR) data.



## Independent, international, open data repository

🔀 protocols.io 🖑

Public, version-controlled protocols



Set data standards for sequence and contextual data (machine-readable)

Galaxy

Open-access data analysis platform

Timme, R.E., Wolfgang, W.J., Balkey, M. et al. One Health Outlook 2, 20 (2020). https://doi.org/10.1186/s42522-020-00026-3

### One Health Enteric package scope





#### CORE attributes

- Isolate identifiers
- Collected by
- Date of collection
- Geographic location
- Sampling purpose
- Sampling device
- Project name
- IFSAC category
- Source type
- sequenced by



#### Human/animal host

• Host

#### • Host disease

- Host sex + age
- Host tissue sampled
- Animal environment
- Antimicrobials in food
- Animal housing system



#### Food samples

- Geographic origin
- Intended consumer
- Collection site description
- Food product type
- Label claims
- Food source
- Food processing types
- Food preservation process
- Food additives
- Food contact surface
- Food container wrapping
- Food container integrity



#### Food facility

- Facility type
- Building setting
- Food processed
- Facility location
- Monitoring zone
- Indoor sampling surface
- Surface material
- Surface material cond.
- Surface orientation
- Surface temperature
- Biocide used
- Animal intrusion



#### Farm and Environment

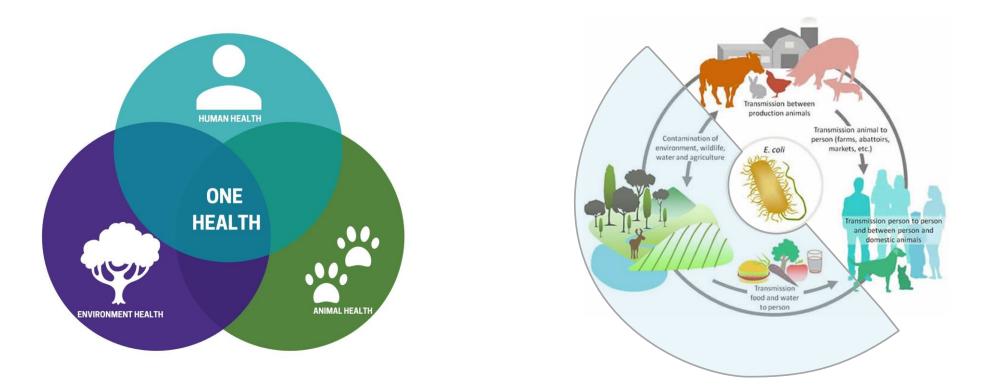
- ENVO triad
- Farm type
- Plant growth medium
- watering method
- Relative loc of sample
- Fertilizer administration
- Food cleaning process
- Sanitizer used
- Farm equip. used
- Water samples
- Extreme weather event
- Mechanical damage

### **One Health Enteric**

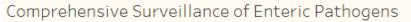
An official website of the United States government Here's how you know >							
NIH National Library of Medicine National Center for Biotechnology Information							
BioSample	BioSample C Search						
BioSample Packages							
A package represents a type of BioSample and specifies the list of attributes by which it should be described. Several BioSample packages are defined in the database.							
You can download the package details in <u>xml format</u> .							
The following information is stored for BioSample Packages:							
Name DisplayName ShortName EnvPackage Description Example	Canonical name and version of the package. Human-readable display name and version of the package. Short name of the core package. Ancillary environmental package (used only for MIxS packages). Definition of the package. Example record.						
Ulless submitters should use canonical name, for example: MIGS.ba.air.5.0.							
Standard Packa	ages						
SARS-CoV-2: clinica	al or host-associated; version 1.0						
SARS-CoV-2: wastewater surveillance; version 1.0							
One Health Enteric; version 1.0							
Microbe; version 1.0							
Model organism or animal; version 1.0							
Metagenome or environmental; version 1.0							
Invertebrate; version 1.0							
Human; version 1.0							
Plant; version 1.0							
Virus; version 1.0							
Beta-lactamase; version 1.0							
Pathogen							
Pathogen: clinical or host-associated; version 1.0							
Pathogen: environmental/food/other; version 1.0							

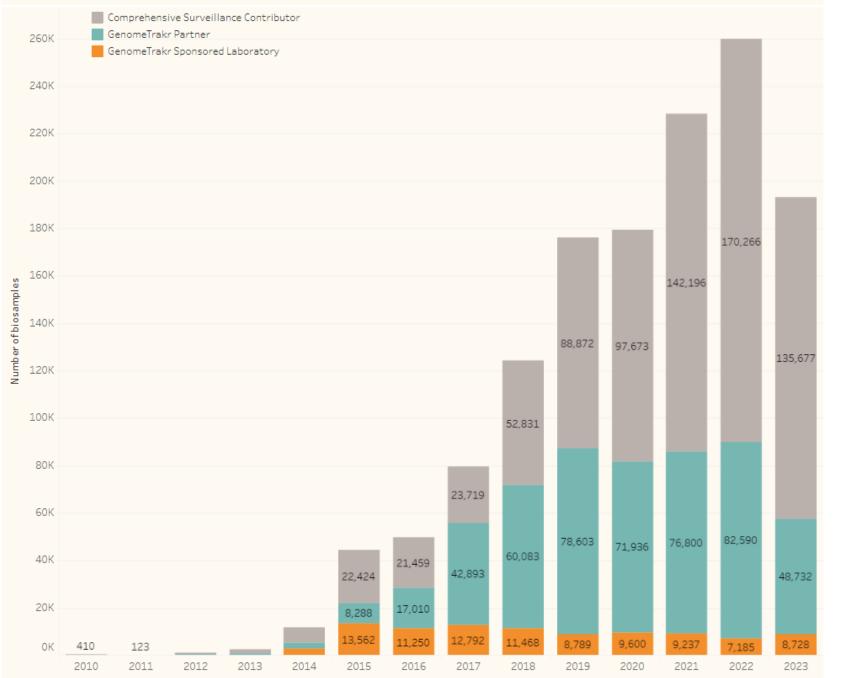
# One Health framework: uniquely important for foodborne pathogens

**Pathogen surveillance:** need to sample the full lifecycle of these pathogens (humans, animals, environment, water, air, food processing plants, food products)



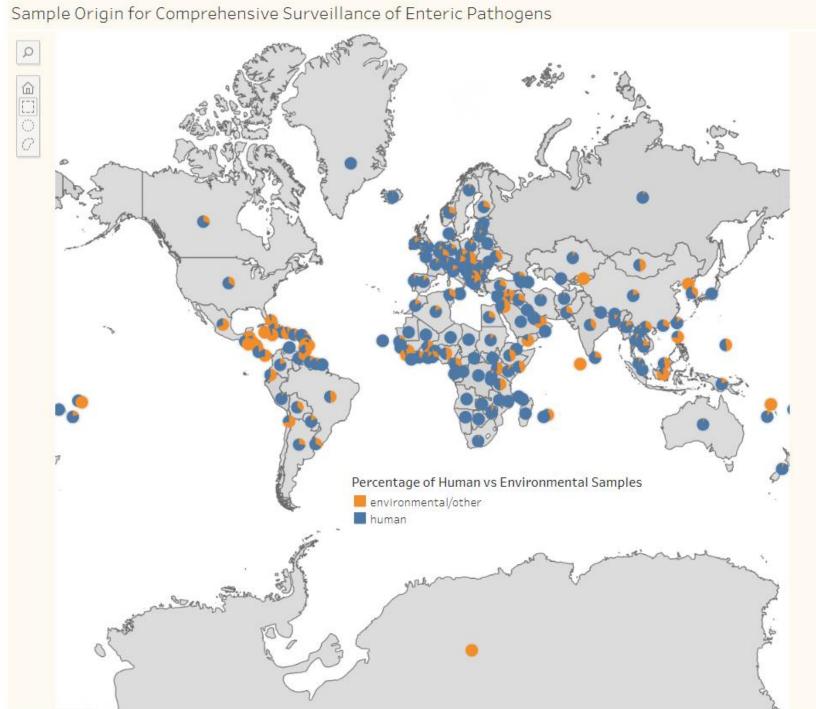
#### **Openly sharing data enables us to traverse the One Health sphere**

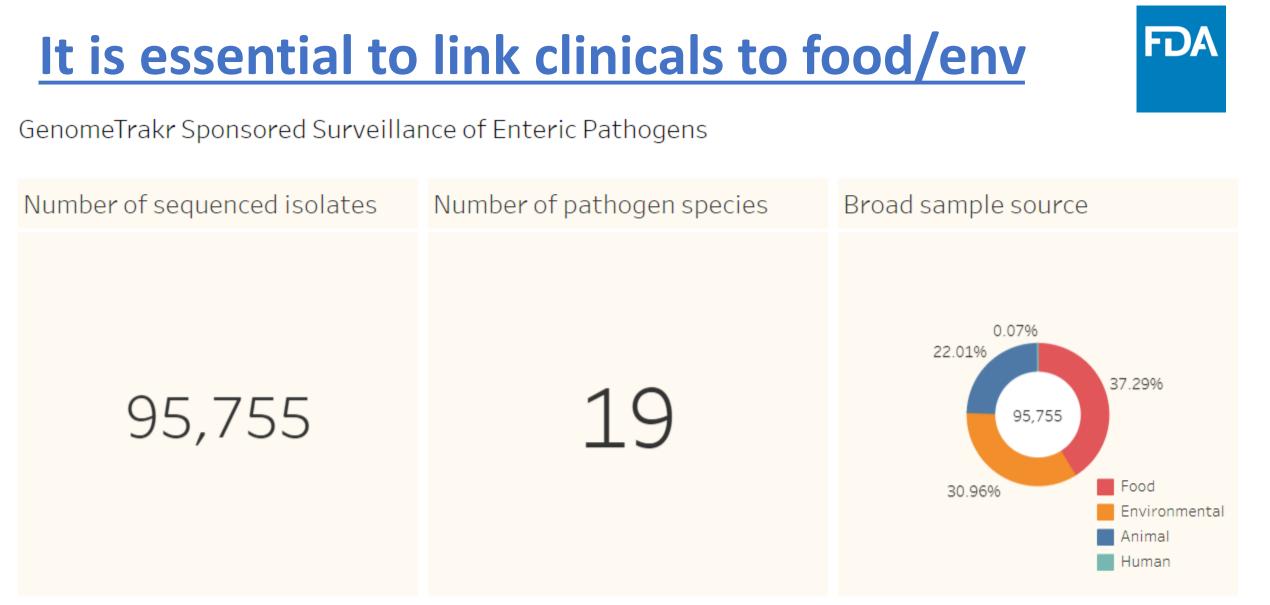




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U.S. GenomeTrakr Sponsored Laboratories

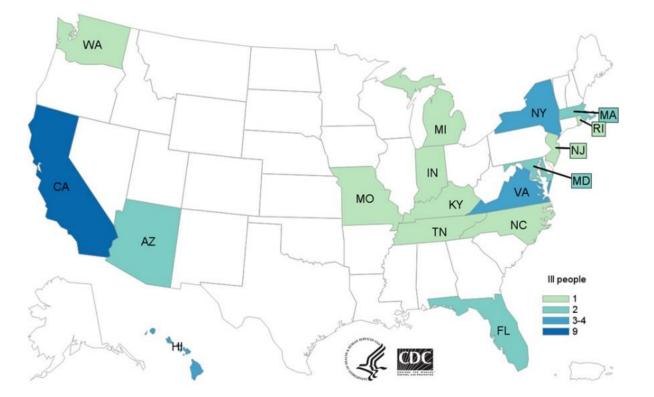
#### Fraction of Isolates Linked to Human Illness by Sample Source Collected by the GenomeTrakr Network

environmental 37.26%	environmental-water 37.54%	<sup>cow</sup> 19.36%	beef	animal feed	fish		pork
		veterinary clinical/research cow <b>29.42%</b>	herbs <b>19.46%</b>			pig	nuts
	chicken 48.62%		other animal 24.27%				
veterinary clinical/research   other animal <b>41.37%</b>		veterinary clinical/research pig <b>20.66%</b>	veterinary		fungi		
	environmental-factory/production facility <b>35.28%</b>		dairy <b>30.85%</b>	poultry			
		turkey 58.73%	vegetable row crops		grains		



### Case Study: First LM outbreak (ultimately linked to Enoki Mushrooms)

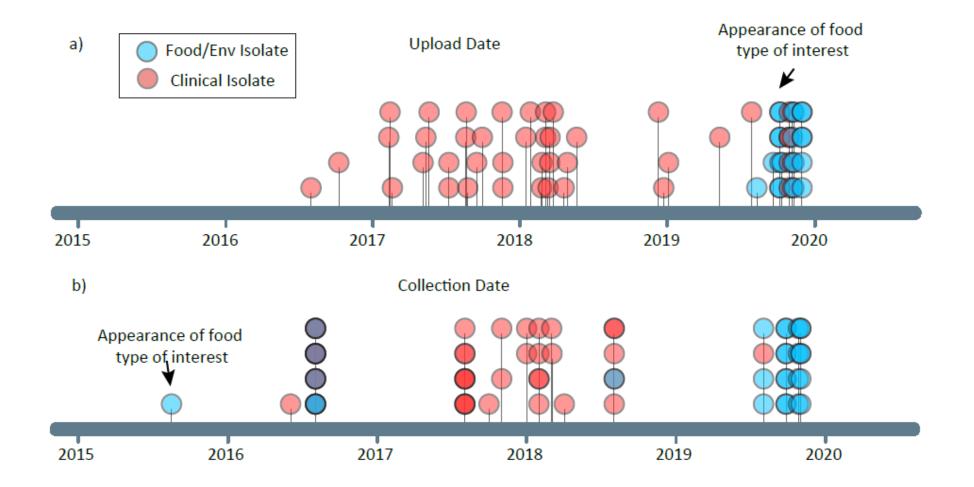
### **Early US Investigation**



- 36 cases in 17 states
- 6 pregnancy-associated cases; 2 fetal losses
- 4 deaths
- Illness Onset dates: Nov. 23, 2016-Dec.13, 2019
  - 2016: 1 case
  - 2017: 18 cases
  - 2018: 17 cases
  - 2019: 6 cases
- Multiple investigations throughout the years; source was not identified
- Epidemiologic signal for Asian-style foods including fresh produce
- Preliminary traceback record review for a positive US State sample of enoki mushrooms identified a manufacturer of interest in the Republic of Korea

### **Collection vs. Upload**





#### The 3 Legged Stool of Foodborne Outbreak Investigations

# FDA

#### Epidemiology

- ~questionaires
- ~interviews
- ~case review
- ~surveillance and reporting
- ~illness clusters
- ~food associations
- ~geographic patterns

Laboratory Support ~pathogen isolation ~identification ~serology ~subtyping -PFGE -WGS

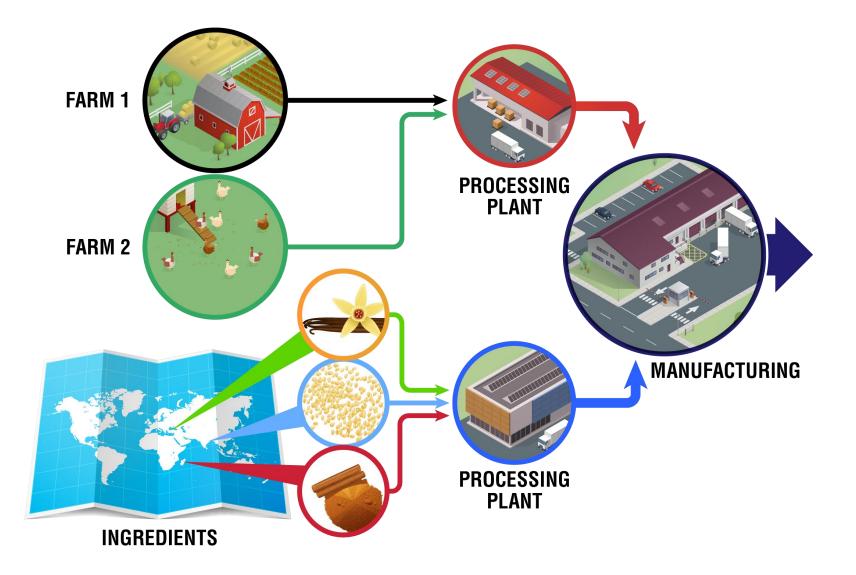
#### Traceback

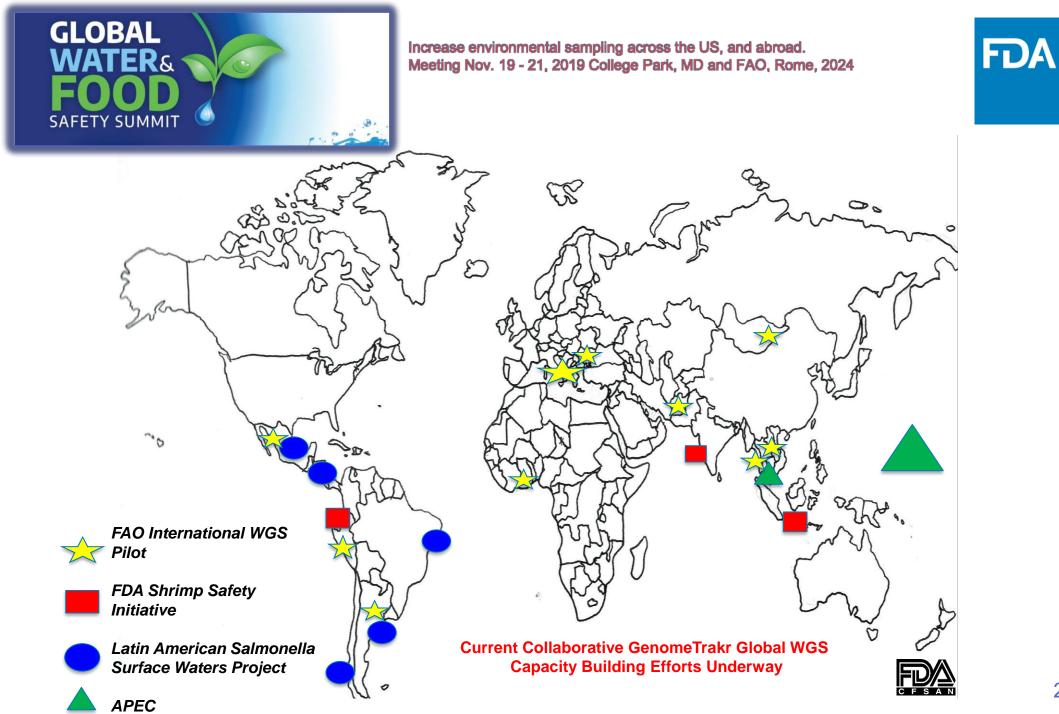
- ~distribution chains/product flow
- ~environmental assessments
- ~potential source reservoirs
- ~GAP/GMP review of HACCPs
- ~Inspectional findings
- ~Risk assessments



### From the Present to the Future: Where do we go and what can we do?

### Identifying Root Cause: Transition to Preventive Controls





### **Economics**



- GenomeTrakr program was likely cost effective by its second year of implementation
- \$100 M -> \$450 M in net annual health benefits (est. from 2019). >\$ Billion estimated benefits.



**Return on Investment:** \$10 dollars in averted human health costs for every \$1 dollar invested. For each additional 1,000 WGS isolates added to the public NCBI database is associated with a reduction of approximately 6 illnesses per WGS pathogen, per year.

### **Metagenomics**

