

# **ISO/WHOLE GENOME SEQUENCING COOPERATIVE AGREEMENT UPDATE**

GenomeTrakr Meeting  
Arlington, VA  
Wednesday, September 26, 2018  
Christina Megalis  
Donald Burr, PhD

# WELCOME

- We are in Year 2 of the ISO/WGS Cooperative Agreement Program (CAP) Bridge Grant
  - July 1, 2018 to June 30, 2019
  - End-of-Year Reports from Year 1 reviewed
  - Notice of Grant Awards sent via eRA Commons
  - 11 of 34 laboratories in CAP awarded WGS funding
    - Same laboratories from Year 1 in Year 2
    - ~\$1.8m awarded this year for WGS
    - 5901 isolates sequenced Year 1 (9/17 - 6/18)

# EXPECTATIONS AND DELIVERABLES

- Mid-year reports due 2/28/19
- Deliverables to meet:
  - Sequence 400 isolates
  - Include all relevant information in reports
  - Monthly update calls
  - Issues obtaining isolates? Contact FDA
- Program ends Summer 2019

# ISO/WGS GRANT NEXT STEPS

- Bridge Grant was intended to bridge funding until launch of the Laboratory Future Funding Model (LFFM)
- FDA hopes to award a one-year ISO/WGS bridge CAP in summer 2019
- FDA hopes to award LFFM grantees in summer 2020

# LFFM PROJECT SCOPE: GOAL

- Combine multiple cooperative agreements into one funding vehicle: LFFM
  - Purpose: to ensure more effective monitoring, oversight, and accountability of the funds
- Developed funding model from internal assessment of current state laboratory portfolio, including various cooperative agreements (CAs), contracts, and FERN



# LFFM OUTREACH ACTIVITIES

Jan 2018 - LFFM workshop at Manufactured Food Regulatory Program (MFRP) Alliance/ISO F2F

March 2018 - LFFM Session at Animal Feed Regulatory Program Standards (AFRPS) CAP Annual F2F

April 2018 - FERN CAP Annual F2F

June 2018 - APHL Annual Meeting

**Sept 2018 - GenomeTrakr F2F**



| Milestone  | Date                    | Status   |
|--|-------------------------|--|
| State lab portfolio assessment completed (Phase I) | 5/30/18                 | Complete   |
| LFFM design drafted (Phase II)                     | 6/29/18                 | <b>Complete</b> - LFFM workgroup drafted scope, criteria and eligibility<br><br><i>(Reviewers include LFFM Advisory Stakeholders, OFVM SCCG, and the ACRA)</i> |
| LFFM design approved (Phase II)                    | September (?) (planned) | <b>In Progress</b> - ACRA to review with Commissioner  |
| FOA drafted (Phase III)                            | May 2019 (planned)      | <b>In Progress</b><br><br><i>(Reviewers include FDA members of the LFFM Advisory Stakeholders, OM, ACRA, and OAGS)</i>   |
| FOA approved and submitted to OAGS (Phase III)     | October 2019 (planned)  | <b>In Queue</b>  |
| New Awards   | Summer 2020 (planned)   | <b>In Queue</b>  |

# PROPOSED SCOPE

- In draft form and undergoing the formal approval process
- Several programs and options were considered for inclusion
- Appropriate structure will be developed to incorporate disciplines and analytical tracks

State labs funded under different CAPs and contracts including:

- FERN (Chemistry, Microbiology & Radiological)
- Whole Genome Sequencing
- ISO supporting MFRPS/AFRPS
- Rapid Response Team
- Sampling contracts



# ELIGIBILITY AND CRITERIA

- Tailoring the flexible funding concept “birthed” by MFRPS
- In development by the LFFM Workgroup
- Reviewed by:
  - Associate Commissioner of Regulatory Affairs (ACRA) and FDA Commissioner
  - LFFM Advisory Stakeholders
  - OFVM Science & Compliance Coordination Group
- Suggestions and ideas from you!

# WE NEED YOUR INPUT

## THINK ABOUT IT

- For future-funded cooperative agreements (supporting micro/chem/rad disciplines, ISO accreditation, WGS, etc):
  - What are the analytical areas of which FDA should focus in terms of sample collection/analysis in the short term? long term?
  - How can FDA collaborate with labs to improve sample collection and analysis?
  - How can FDA collaborate with labs to improve sample delivery systems?
- For the GenomeTrakr program:
  - How can FDA collaborate with labs to improve isolate collection and analysis?
  - How can FDA collaborate with labs to improve isolate delivery systems?
- What are some examples of measurable lab and program performance metrics that FDA could track and monitor to ensure Return on Investment (ROI) of future-funded cooperative agreements?
- Future-funded cooperative agreements from FDA are dependent upon availability of federal appropriations as well as FDA's strategic initiatives. Since federal funds are not guaranteed in perpetuity, what expertise/support is needed in the short term (<5 years) that will facilitate a lab's program sustainability in the long term?

# LFFM STRUCTURE CONSIDERATIONS

- Based on the analytical needs of FDA
  - Incorporate FDA lab initiatives into one funding vehicle
- Dependent upon individual lab capacity/capability
- Flexible funding levels
- Outcome-based metrics

# GT NETWORK: FUTURE OUTLOOK

- FDA is developing a long-term Strategic Plan for FDA labs that will:
  - identify FDA sampling and testing needs for the coming years
  - develop outcome based metrics that funded labs will need to meet
- Opportunity for network expansion in the future, e.g. expand based on geographical needs and high production food areas

# FDA COMMITMENT

- FDA is committed to supporting the GenomeTrakr network
- Desire to expand, factoring:
  - availability of funds
  - agency priorities

# QUESTIONS OR CONCERNS

[christina.megalis@fda.hhs.gov](mailto:christina.megalis@fda.hhs.gov)

