

FDA One Health Broad Agency Announcement Overview and Priorities

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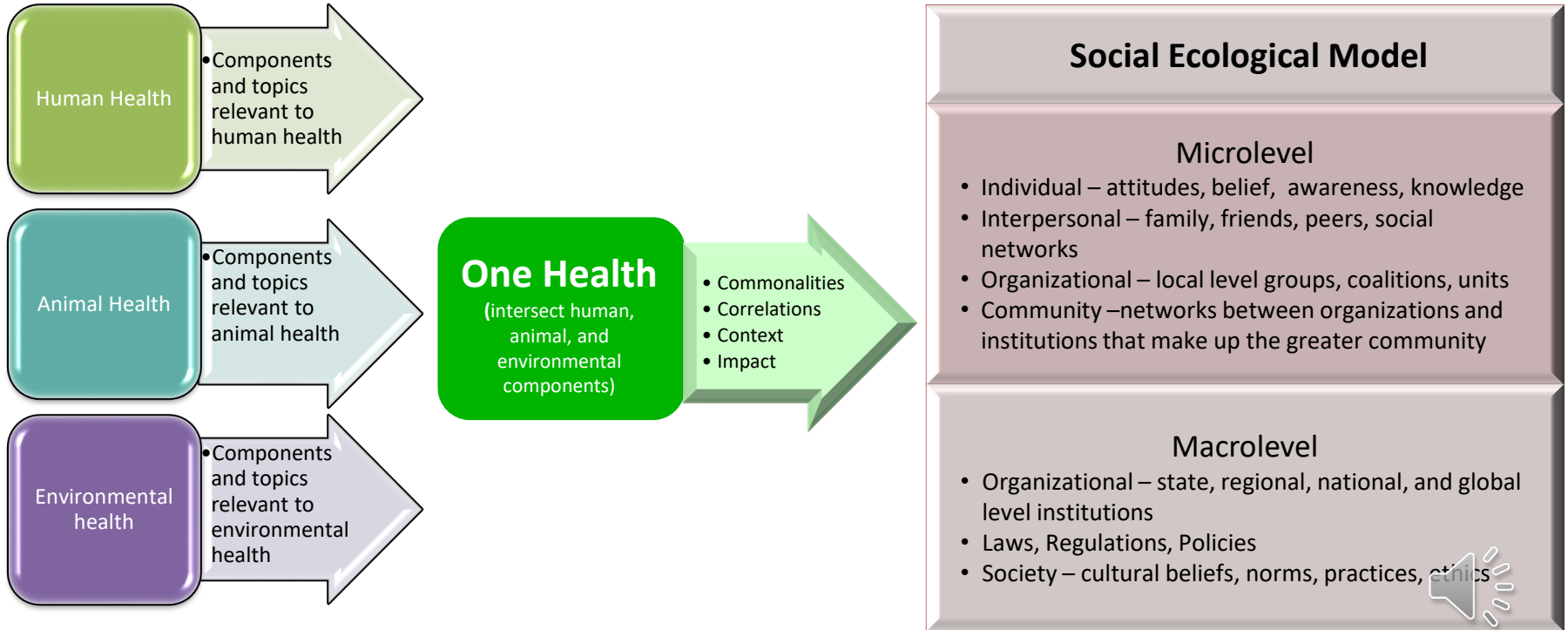
What is One Health?

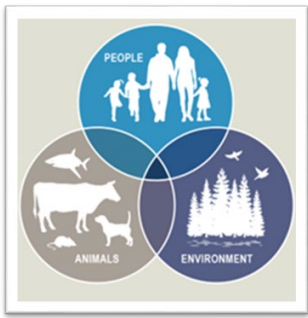
One Health is a collaborative, multisectoral, and trans-disciplinary approach—working at the local, regional, national, and global levels—with the goal of achieving optimal health outcomes recognizing the interconnection between people, animals, plants, and their shared environment.

US Government Definition



Utilizing the One Health Framework





FDA's Regulatory Mission



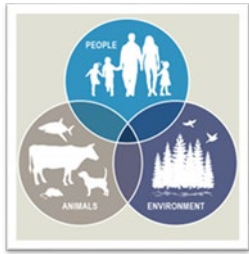
FDA's One Health Initiative

- **FDA One Health Vision** - Optimal public health outcomes for humans and animals in their shared environment.
- **FDA One Health Mission** – FDA collaborates with stakeholders across disciplines and sectors to promote the health of humans, animals, and the environment using science, technology, and innovation.



Priority	Call to Action for the Biomedical Science Community
Sustain workforce	<ul style="list-style-type: none"> Consider career or term working at FDA Support collaboration with FDA employees Build regulatory and translational science into curricula
COVID pandemic response	<ul style="list-style-type: none"> Continue adaptive approach to understanding the virus, pandemic, and interventions
Substance use disorder and overdose	<ul style="list-style-type: none"> Renew focus on pain and its treatment Renew focus on substance use disorder and its treatment
Cancer	<ul style="list-style-type: none"> All hands on deck for translation of science into effective interventions
Gene therapies	<ul style="list-style-type: none"> As the science of genetic modification for medical products, food products, and animal health continues to accelerate, advances in translational science are needed to understand off-target and long-term effects of acute interventions
Common chronic diseases	<ul style="list-style-type: none"> Without losing ground on cancer and rare disease, a renaissance is needed to develop both broad preventive and precision interventions for chronic diseases, including mental health
Tobacco	<ul style="list-style-type: none"> Elevate science of addiction and nicotine dependence Support cessation of tobacco product use Improve support for those attempting to quit
Digital transformation	<ul style="list-style-type: none"> Develop approaches to digitization that preserve integrity of data and privacy but unlock measurement in "real life" on a more continuous basis Improve infrastructure, methods and capabilities for managing, sharing, transferring and analyzing data
Food	<ul style="list-style-type: none"> Focus on sustainable agriculture Improve knowledge of nutrition Move into a new era of food safety, driven by digitized information about the supply chain and biological science Foster public interaction to unlock the potential of intentional genetic modification and other novel technologies on food supply and nutrition in a time of climate change
Misinformation	<ul style="list-style-type: none"> Join the effort to preempt and rebut misinformation, learn to translate science into understandable language, and promote reliable and accurate information
One Health and the global environment	<ul style="list-style-type: none"> Share data on a national and global basis for surveillance Learn from the interdependencies by sharing and connecting appropriate data Remove the bottlenecks for responsible sharing Develop appropriate safeguards to protect privacy while sharing data to improve health

Priority	Call to Action for the Clinical Community
Pandemic response	<ul style="list-style-type: none"> Focus on effective implementation of vaccination and rapid antiviral treatment Seek out opportunities for taking part in basic and clinical studies to provide reliable evidence for prevention and treatment, including "Long COVID"
Substance use disorder and overdose	<ul style="list-style-type: none"> Elevate priority of appropriate opioid prescribing and treatment of addiction and overdose Support research into pain mechanisms and clinical trials of nonaddictive pain therapies
Tobacco use	<ul style="list-style-type: none"> Bring awareness of tobacco to the fore in the clinical community Develop better approaches to cessation treatment, counseling, and support of individuals trying to quit
Cancer	<ul style="list-style-type: none"> Support Cancer Moonshot to translate scientific advances into effective treatment
Rare diseases	<ul style="list-style-type: none"> Participate in translational studies Develop system of post-market evaluation to understand long-term effects of genetic modification
Common chronic diseases	<ul style="list-style-type: none"> Improve adherence to proven effective primary and secondary prevention interventions Participate in pragmatic trials to develop new interventions at lower cost Participate in disease surveillance
One Health	<ul style="list-style-type: none"> Reduce inappropriate antibiotic prescriptions
Sustain workforce	<ul style="list-style-type: none"> Develop attractive hybrid workplace including virtual and in-person interactions Encourage FDA participation in scientific and clinical meetings Support regulatory science in curricula Participate in advisory committees
Evidence generation	<ul style="list-style-type: none"> Create priority-driven networks of clinicians and patients Engage support from professional, academic, and health system leadership
Consortia development	<ul style="list-style-type: none"> Actively bring together patients, families, and clinicians Promote evidence development and use of proven effective interventions
Testing and digitization	<ul style="list-style-type: none"> Ensure proper evaluation of digital interventions and tests Education about probabilistic information to guide decisions
Equity	<ul style="list-style-type: none"> Actively and intentionally correct disparities related to race and ethnicity, sex, gender, age, and social determinants (including wealth, education, and rurality)
Misinformation	<ul style="list-style-type: none"> Actively participate in dissemination of reliable information Actively refute misinformation



FDA One Health Priorities

- **Research in response to the ongoing Avian Influenza A (H5N1) outbreak**
- Product-safety topics: food, drug, device, tobacco
- Antibiotic resistance
- Pandemic-related topics
- Technology/Innovation/Practices
- Regulatory/Enforcement topics
- Building capacity and resource needs

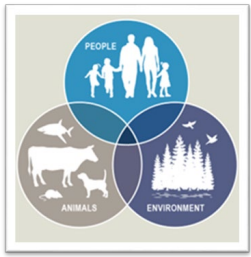




Recommended Considerations for Future Projects

- **Proposals must utilize the One Health approach**
 - health and well-being of humans and animals in their shared environment are important.
- **Must align with FDA's regulatory mission.**
- Should align with FDA's One Health vision and mission.
- Should align with FDA's One Health priorities.
- Should include cross-cutting and multidisciplinary public health priorities within the Agency or across FDA Centers/Offices.





Examples of FDA One Health Activities

- Note: These examples do not represent the entire FDA One Health research portfolio or research priorities:
 - Utilization of information and safety data that predicts and communicates health risks across species contributing to the establishment of policies, technology, and innovation.
 - Utilize subject matter expertise, equipment, and facilities for effective health education, communication, and training.
 - Research and surveillance improving response to emerging threats through supporting the development of human and veterinary medical products.



More Information

- <https://www.fda.gov/science-research/focus-areas-regulatory-science-report/cross-cutting-topics-one-health-initiative>
- <https://www.fda.gov/food/alerts-advisories-safety-information/updates-highly-pathogenic-avian-influenza-hpai>
- <https://www.fda.gov/science-research/fda-grand-rounds/fda-grand-rounds-one-health-fda-concept-application-07142022>
- <https://www.fda.gov/animal-veterinary/cvm-updates/fda-announces-animal-and-veterinary-innovation-centers-partnerships>
- <https://www.fda.gov/science-research/fda-grand-rounds/pandemic-and-call-action-one-health-fda-one-health-initiative-06112020-06112020>
- <https://content.govdelivery.com/accounts/USFDA/bulletins/335bbf4>
- <https://www.fda.gov/animal-veterinary/science-research/how-we-conduct-one-health-monitoring-and-investigation>
- <https://www.fda.gov/news-events/press-announcements/fda-supports-innovation-animal-biotechnology-veterinary-products-food-animals-through-new>





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