
Overview of the WIHS

WOMEN'S INTERAGENCY HIV STUDY
Semiannual Executive Committee Meeting

May 19, 2016
Rockville, Maryland



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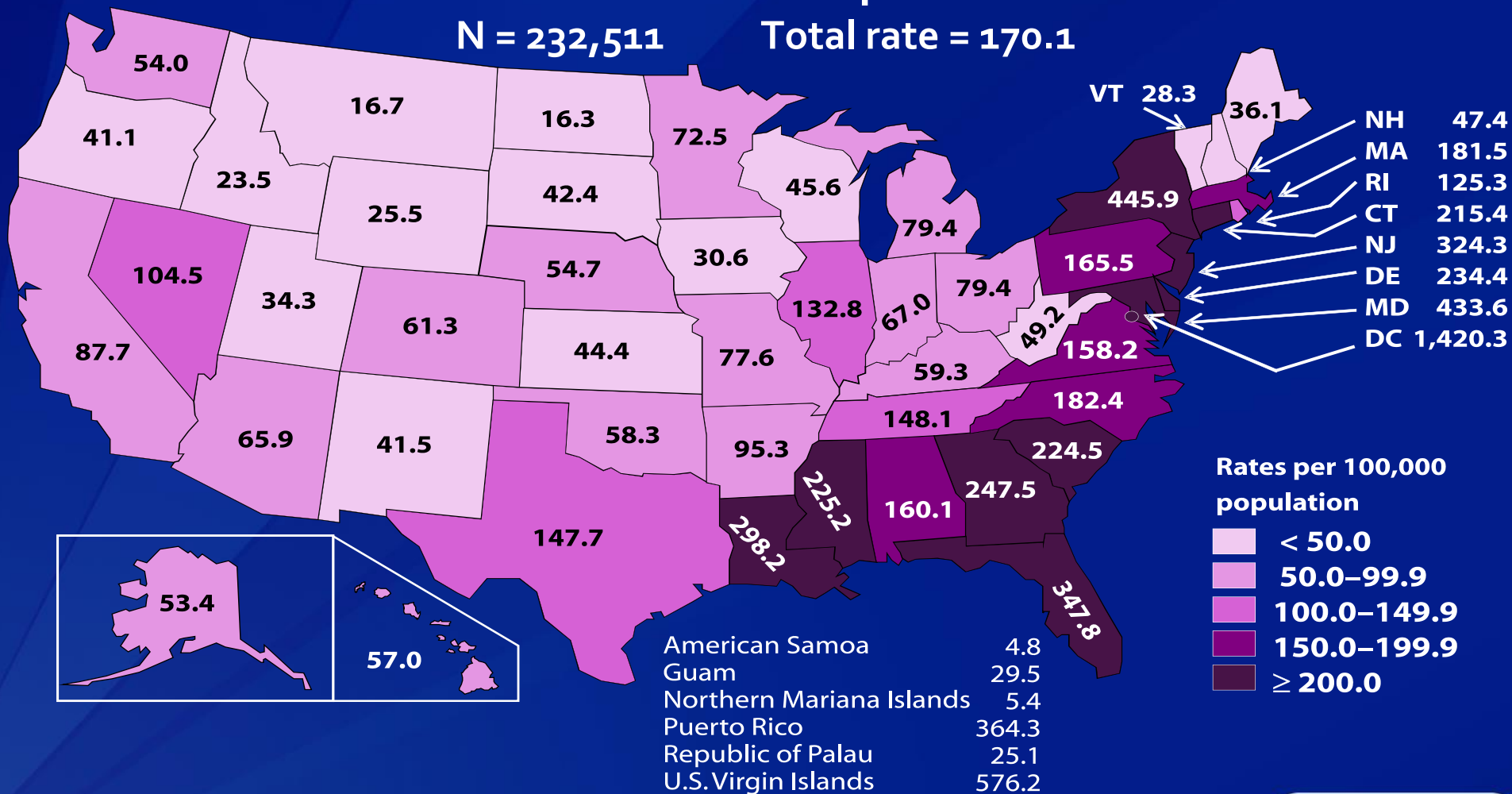
Women's Interagency HIV Study (WIHS) Sites



Rates of Adult and Adolescent Females Living with Diagnosed HIV Infection, Year-end 2013— United States and 6 Dependent Areas

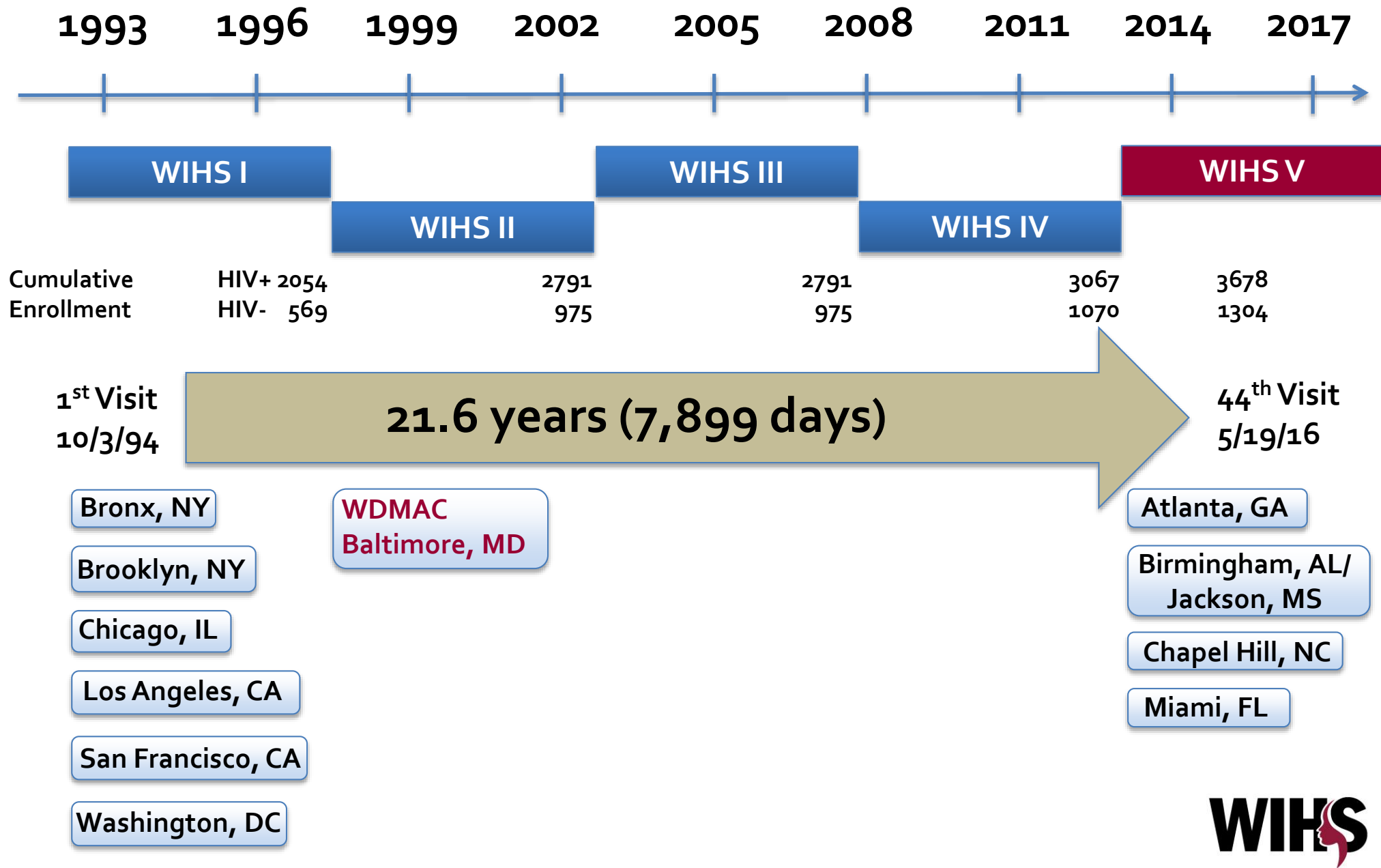
N = 232,511

Total rate = 170.1



Note. Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays, but not for incomplete reporting.

WIHS Timeline



WIHS Sites and Principal Investigators

▶ **Clinical Sites:**

- Atlanta, Georgia (*I. Ofotokun, G. Wingood*)
- Birmingham, Alabama/Jackson, Mississippi (*M. Saag, M. Kempf, D. Konkle-Parker*)
- Bronx, New York (*K. Anastos*)
- Brooklyn, New York (*H. Minkoff, D. Gustafson*)
- Chapel Hill, North Carolina (*A. Adimora*)
- Chicago, Illinois (*M. Cohen, A. French*)
- Los Angeles, California (*J. Milam*)
- Miami, Florida (*M. Fischl, L. Metsch*)
- Northern California (*R. Greenblatt, P. Tien, B. Aouizerat*)
- Washington, D.C. (*S. Kassaye*)

▶ **Data Coordinating Center (WDMAC):**

- Johns Hopkins University, Baltimore, Maryland (*S. Gange, E. Golub*)

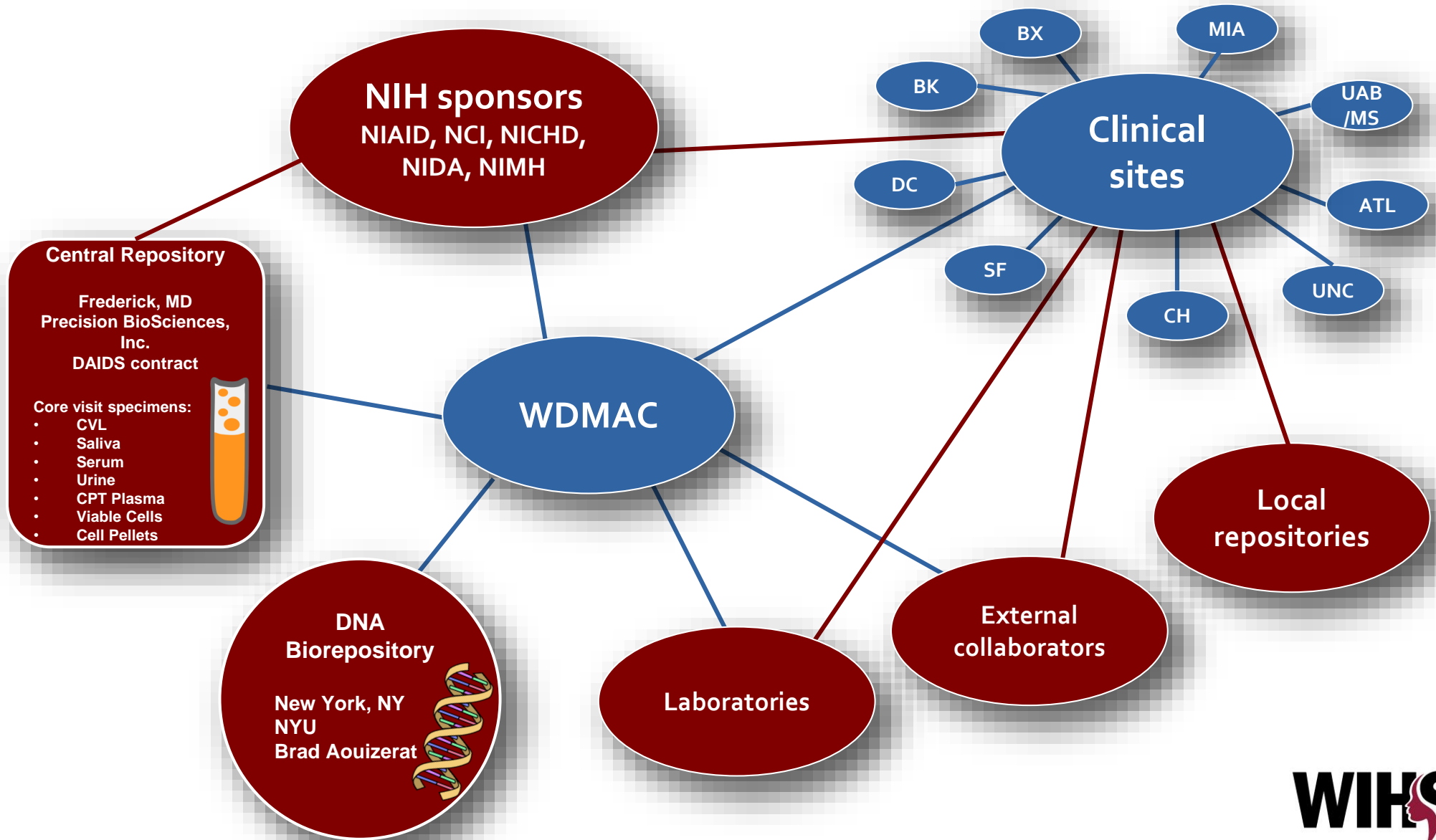
WIHS Sponsoring Institutions (Program Officers)

- ▶ **National Institute of Allergy and Infectious Diseases** (*J. Roe*)
 - **National Cancer Institute** (*G. Dominguez*)
 - ***Eunice Kennedy Shriver* National Institute of Child Health and Human Development** (*D. Russo*)
 - **National Institute on Drug Abuse** (*K. Davenny, R. Jenkins*)
 - **National Institute of Mental Health** (*D. Colosi*)

Areas of Focused Scientific Research in WIHS-V

- ▶ Aging
- ▶ Behavior & Substance Use
- ▶ Cancer
- ▶ Epidemiology
- ▶ Female Genital Tract & Pathogenesis
- ▶ Genetics
- ▶ Gynecology
- ▶ Hepatitis & Liver Disease
- ▶ Human Papillomavirus
- ▶ Metabolics & Renal Disease
- ▶ Neurocognition
- ▶ Pharmacokinetics & Antiretroviral Exposure
- ▶ Pregnancy

The World WIHS Web



Design Strengths of WIHS

- *WIHS implements standardized protocols that prospectively collect:*
 - + *Important contributors to HIV disease (labs, meds, outcomes)*
 - + *Novel measures not routinely collected in clinical care settings*
 - + *Comparable data on HIV-uninfected women*
- *Visit components reviewed and updated every six months*

Semi-Annual Visit

- ▶ Interviewer-administered Questionnaires:
 - Behavior
 - Medical and OB/GYN History
 - Health Services
 - Demographics/Psychosocial
- ▶ Physical and Gynecological Examination, including annual neuropathy assessment
- ▶ Annual Lipodystrophy Exam (body measures, BIA)
- ▶ Medication use (ART, OI prophylaxis, hepatitis, etc.)

Design Strengths of WIHS

- *WIHS collects extensive biological specimens at each visit:*
 - + *Blood (virologic, immunologic, fasting lipid markers, liver/renal function, etc.)*
 - + *Other (CVL, saliva, urine)*
 - + *Local and National Repositories*
- *Nested substudies that capitalize on the size and depth of WIHS can be easily implemented*

Committed Specimens

As of 4/13/2016

Total ever	3,019,686 (+ 2%)
Not Available	336,591
Shipped	330,952 (+ 7,764) 11% utilization
To be Shipped ^a	209
Unusable ^b	5,430 (+ 14)
Incoming Temp Storage	0
Currently Available	2,683,095



^a Less than four weeks since submitted for withdrawal

^b Discrepant, destroyed, broken, empty, lost, or missing



Current Core Follow-up Visit Components

- Specimen collection
- Interview (core and substudy forms)
- Exams
 - Neuropathy assessment*
 - Physical exam
 - Ankle brachial index**
 - Gynecological exam & specimen collection
 - Frailty assessment*
- Neurocognitive Battery**

*Annual administration

**Once every two years

Neurocognitive Battery

- Lawton Instrumental Activities of Daily Living (*IADL-LF/SF*)
- Hopkins Verbal Learning Task – Revised, Immediate Recall Trials
- Stroop
- Trail Making Test
- Symbol Digit Modalities Task
- Hopkins Verbal Learning Task – Revised, Delayed Recall and Recognition Trials
- Verbal Fluency
- Letter Number Sequencing Task
- Grooved Pegboard
- Stress Assessment Questionnaire

Follow-up Interview Forms

- Sociodemographics
- Follow-up Health History
- Hospitalizations
- Autoimmune Disease
- Medication History
 - Antiretroviral Medication Use
 - OI Prophylaxis Medication Use
 - Hepatitis Medication Use
- OB/GYN and Contraceptive History
- Menopause Symptom Questionnaire
- Alcohol, Drug Use and Sexual Behavior
- Health Care Utilization
- Engagement in Care
- Psychosocial Measures
- San Diego Claudication Questionnaire
- Physical Activity Questionnaire
- Brief Pain Inventory
- Pain Medication Use
- Women's Adherence and Visit Engagement
- Oral Health
- Mobile/Internet Technology

Forms completed only if participant on meds

Women > 39 yo only, once every 2 years

Substudy (non-core) interview forms



Follow-up Exam Components

- Neuropathy Assessment
- Weight
- Height
- Circumference Measures
- Bioelectric Impedance Analysis
- Frailty Assessment (chair stands, 4-meter walk, grip strength)
- Ankle Brachial Index
- Breast Exam
- Blood Pressure
- Gynecological Exam
- Abnormality/Lesion Assessment
- Wet Prep/Saline Mount
- KOH Mount
- Pap

Annual administration

Women > 39 yo only, once every 2 years

Women > 39 yo, annual administration

Specimen Collection & Laboratory

- Specimen Collection:
 - Blood specimen collection
 - Physical exam specimen collection (e.g., urine, cervical vaginal lavage, hair)
 - ARV usage assessment at time of phlebotomy
- Local Laboratory:
 - Performed at site's local laboratory (e.g., *CD4, liver/renal chemistries*)
- Central Laboratory:
 - Performed centrally for all participants (e.g., *Pap, HIV RNA*)

WIHS Data Cleaning

Range check
skip patterns



Data Entry



Sites conduct
pre-edit data check



Central Edits



**Return problems/edits
to site for resolution**



**Return to WDMAC
Review changes**

**Repeat as
necessary**

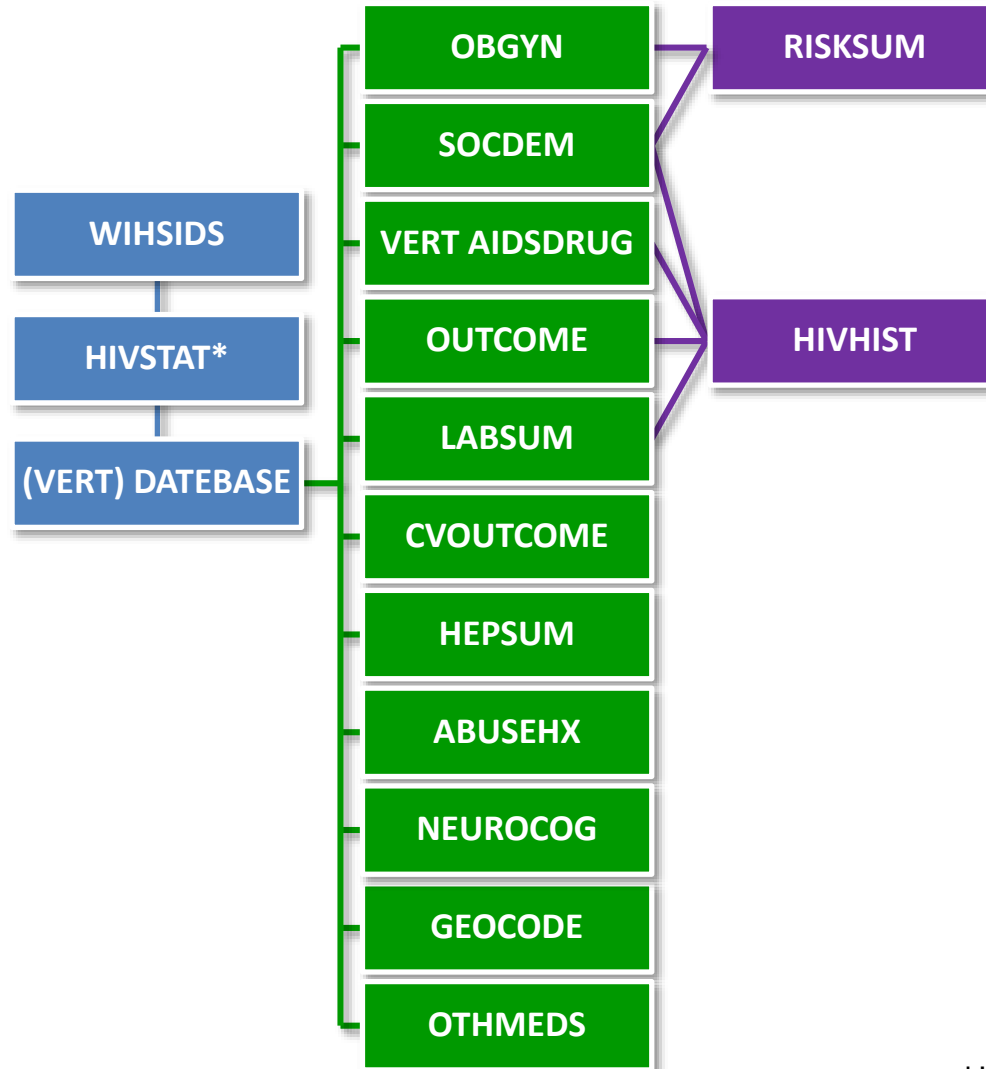


Raw data Files

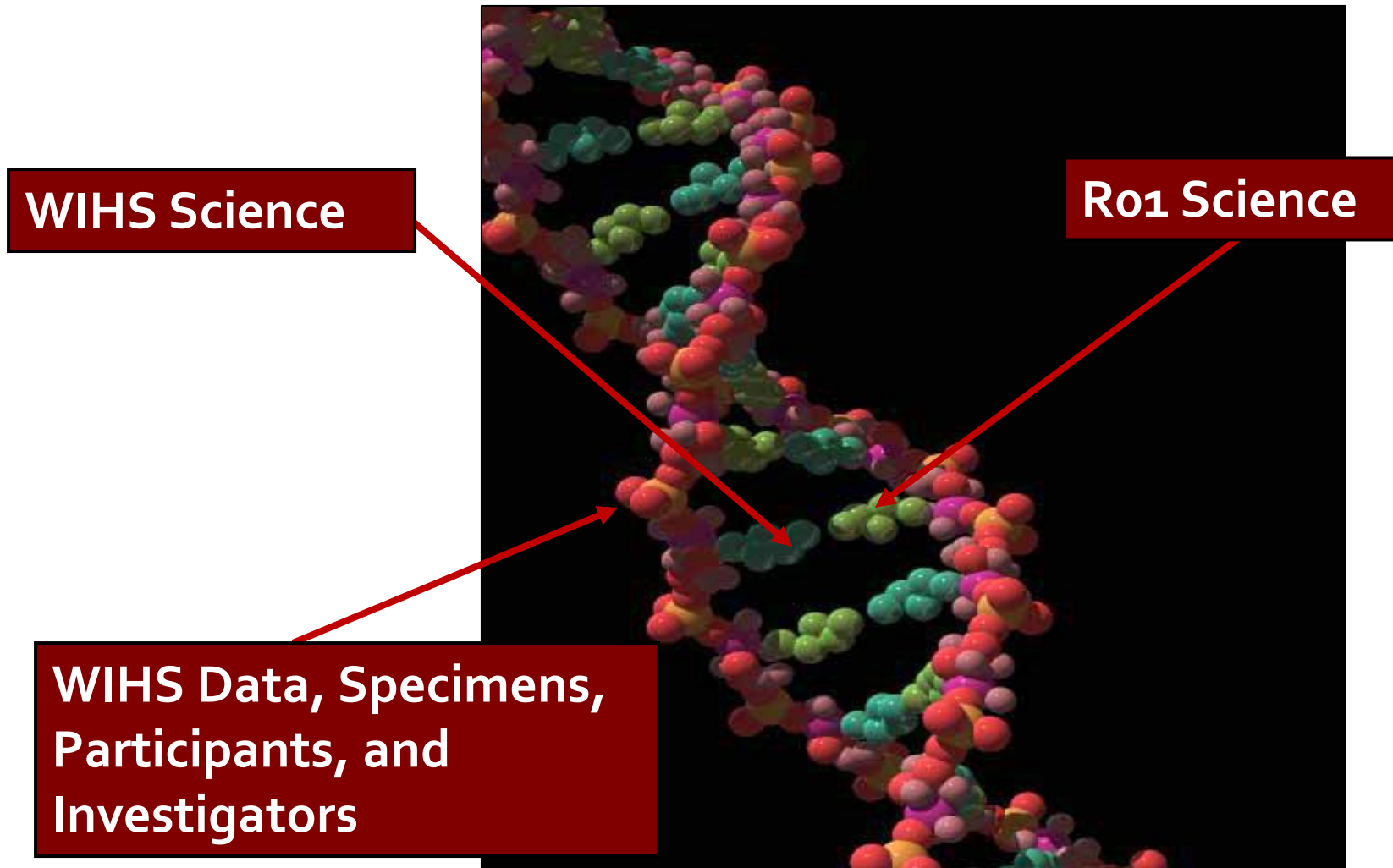


Summary Files

WIHS Summary Files



Linked Awards



Current Major Substudies

- ***Liver Disease and Reproductive Aging*** : Association of HIV, HCV, the menopausal transition and metabolic and inflammatory mediators with liver steatosis and liver fibrosis progression
 - Fibroscan
- ***Immunologic and Clinical Consequences of Hepatitis C***: Effect of HCV cure on neurocognitive consequences and on markers of monocyte/macrophage activation
 - Fibroscan, HCV RNA testing after completion of HCV treatment
- ***Aging and Frailty***: Characterization of potential changes in physical impairment and frailty
 - Repeated chair stands, timed 4-meter walk, grip strength measurement
- ***Effects of HIV and the Menopausal Transition on Musculoskeletal Health***: Assessment of women undergoing the menopausal transition with detailed musculoskeletal studies performed using DXA scanning, Quantitative CT and functional performance tests
 - Repeated chair stands, timed 4-meter walk, grip strength assessment, standing balance, 400-meter walk
- ***Neurocognition***: Assessment of stress, activities of daily living, cognition and functional ability
 - Verbal memory, executive function, psychomotor speed, attention/concentration, fine motor control
- ***HIV, Vascular Injury, and Physical Function***: Measure peripheral arterial disease (PAD) to determine the factors associated with PAD and its progression
 - Ankle brachial index (ABI), physical activity questionnaire, San Diego Claudication Survey
- ***Cervical Cancer Screening Substudy***: Comparison of the accuracy of different molecular assays for cervical cancer screening
 - ThinPrep Pap smear, testing for oncHPV

The Women's Interagency HIV Study (WIHS) is the largest ongoing prospective cohort study of HIV among women in the U.S.

The Women's Interagency HIV Study (WIHS) is a large, comprehensive prospective cohort study designed to investigate the progression of HIV disease in women. The WIHS began in 1993 in response to growing concern about the impact of HIV on women. The core study visit includes a detailed and structured interview, physical and gynecologic examinations, and laboratory testing. After more than 20 years, the WIHS continues to investigate questions at the forefront of HIV research, spanning topics such as women's reproductive health, clinical outcomes (for example, cardiovascular disease, diabetes, and others), and the effectiveness of antiretroviral therapy.

The **WIHS Dossier** provides key summary statistics about the study and the **WIHS Archives** provides a list of all WIHS publications.

