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WORLD CONGRESS OF EPIDEMIOLOGY 2024

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生殖医学国家重点实验室
State Key Laboratory of Reproductive Medicine

Promoting emerging alternatives and modern methodologies

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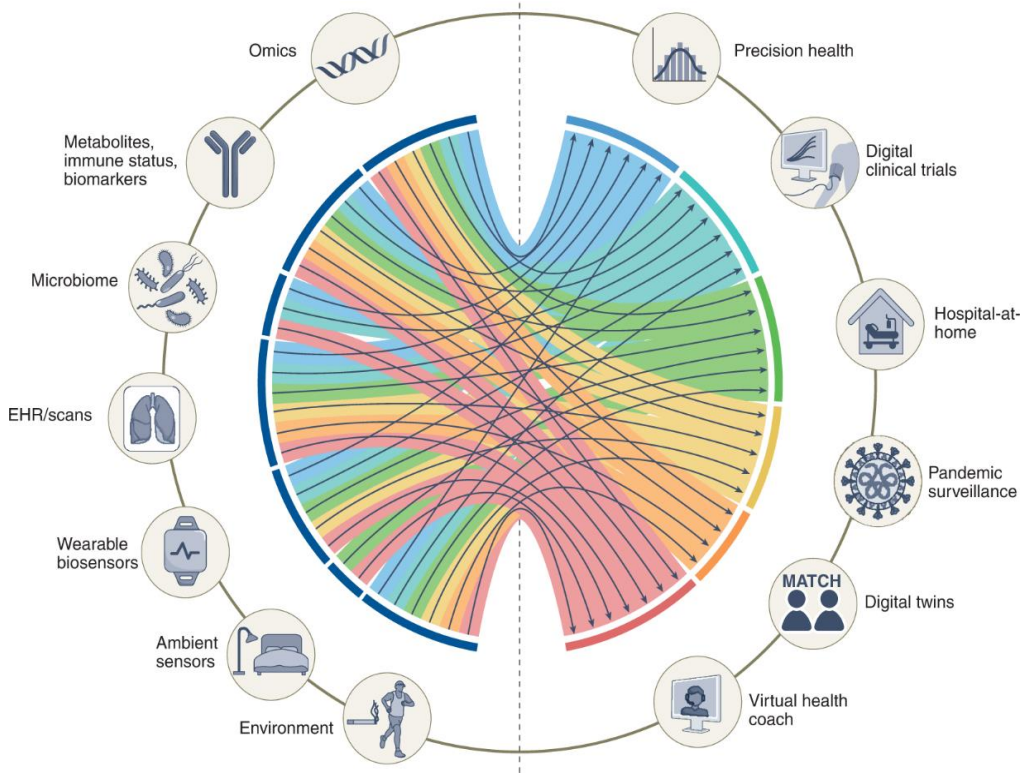
September, 2024, Cape Town

Traditional Cohort *vs.* Modern Cohort

- **Traditional cohort studies** primarily focus on the associations between **macro-level factors** and outcomes.

- **Macro-level factors:** demographics (*e.g.*, gender, age, education), lifestyle (*e.g.*, physical activity, smoking), environmental exposures, etc.

- **Modern cohort studies gather rich population data**, creating a comprehensive database resource.



Support multidisciplinary research and advance public health and medicine

What alternatives / modern methodologies & Why?

1. Omics and Multi-Omics
2. eCohorts and Remote Data Collection
3. Wearable Devices
4. Artificial Intelligence
5. A Brief Introduction of the Jiangsu Birth Cohort Study

What alternatives / modern methodologies & Why?

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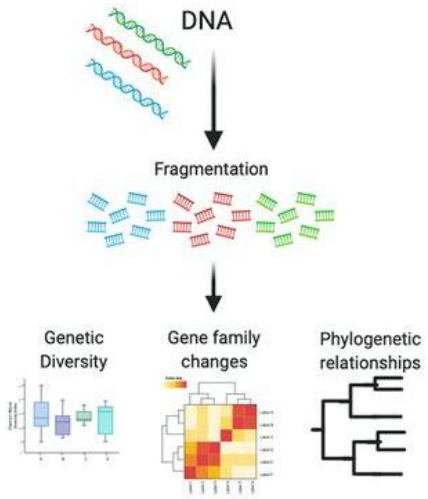
5. A Brief Introduction of the Jiangsu Birth Cohort Study

Previous cohort studies primarily focused on macro-level factors (e.g., lifestyle) without incorporating molecular data (e.g., genomics, proteomics). This limits the depth of insights into disease mechanisms and individual variability.

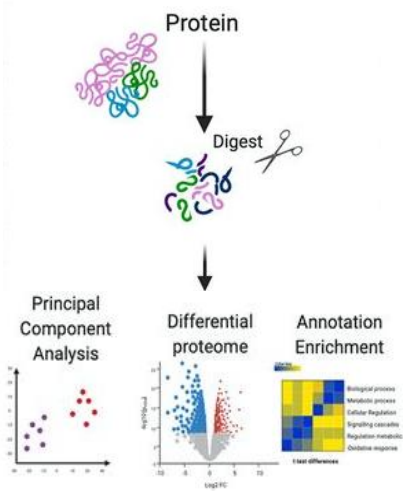
Omics and Multi-Omics| Overview



1

Genomics
1986
Thomas H. Roderick

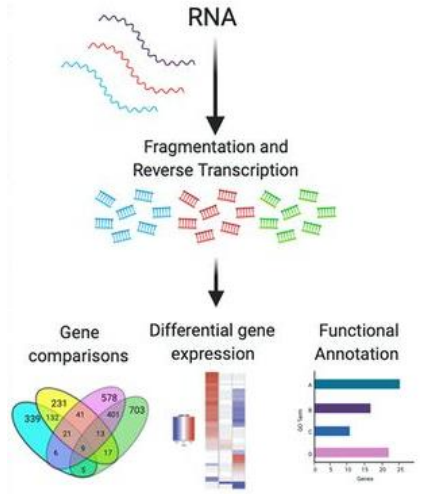
Focus on genome structure, function, and variations related to disease



2

Proteomics
1994
Marc Wilkins

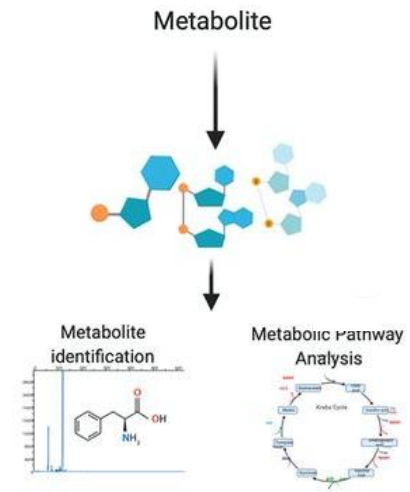
Investigate the composition and variation of proteins within cells, tissues, or organisms



3

Transcriptomics
1999
Charles Auffray

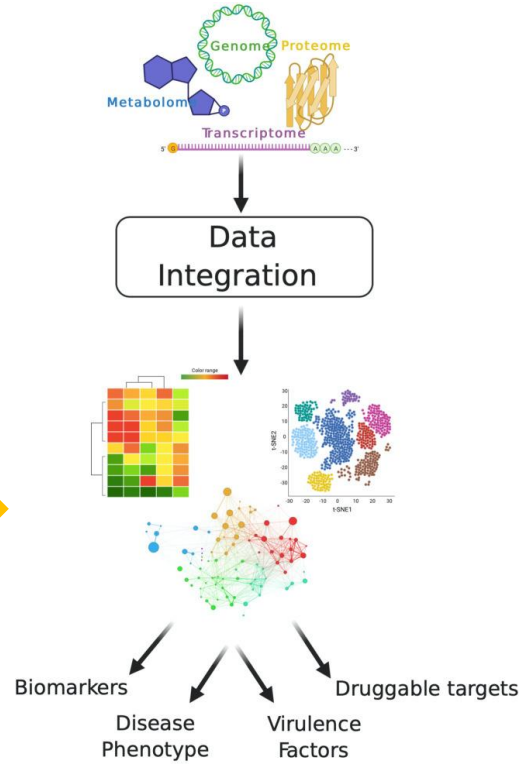
Examine gene expression profiles to reflect physiological states



4

Metabolomics
1999
Nicholson

Map metabolic responses to external stimuli and environmental changes



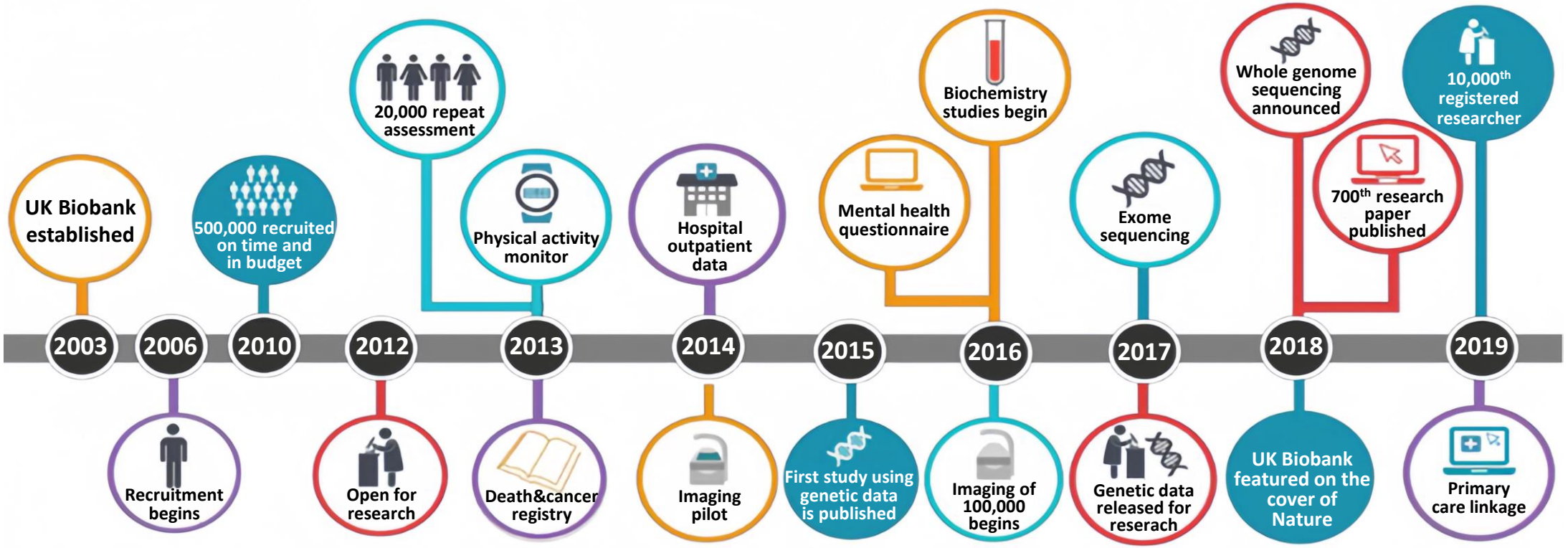
Multi-Omics

mBio. 2020;11(5):e01020-20

Omics and Multi-Omics| UK Biobank

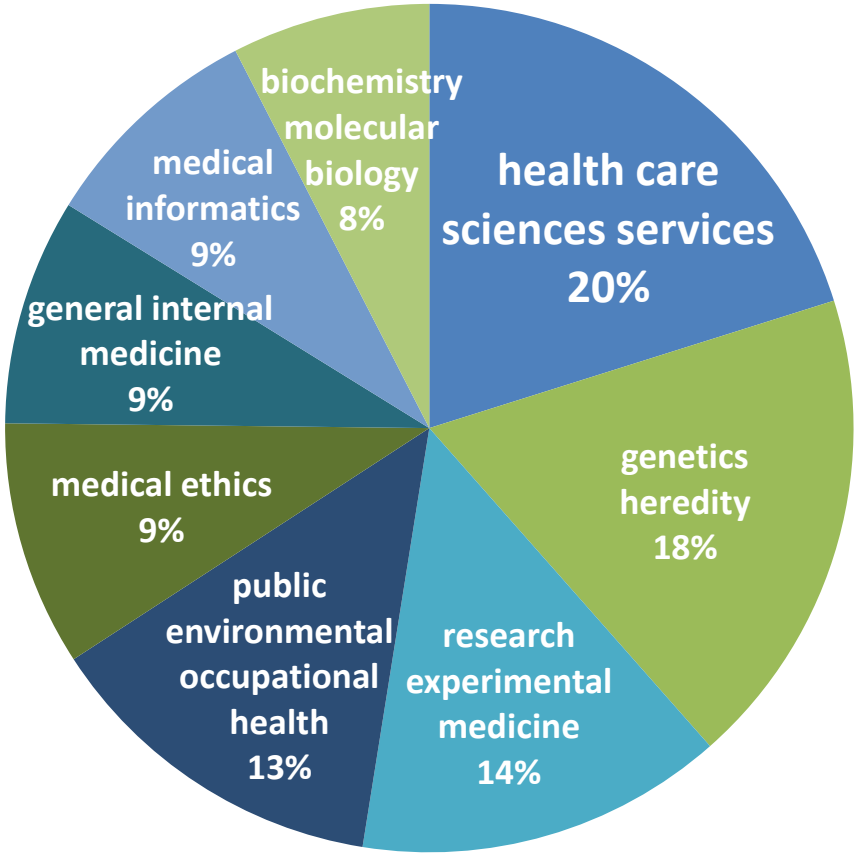
biobank uk
Research Analysis Platform
Enabled by DNAnexus

- **The UK Biobank (UKB)** is a large-scale biomedical database and research resource, established as a prospective epidemiological cohort study.
- It has collected data from 500,000 volunteers across the UK, including genetic data, multimodal imaging, and health-related information.

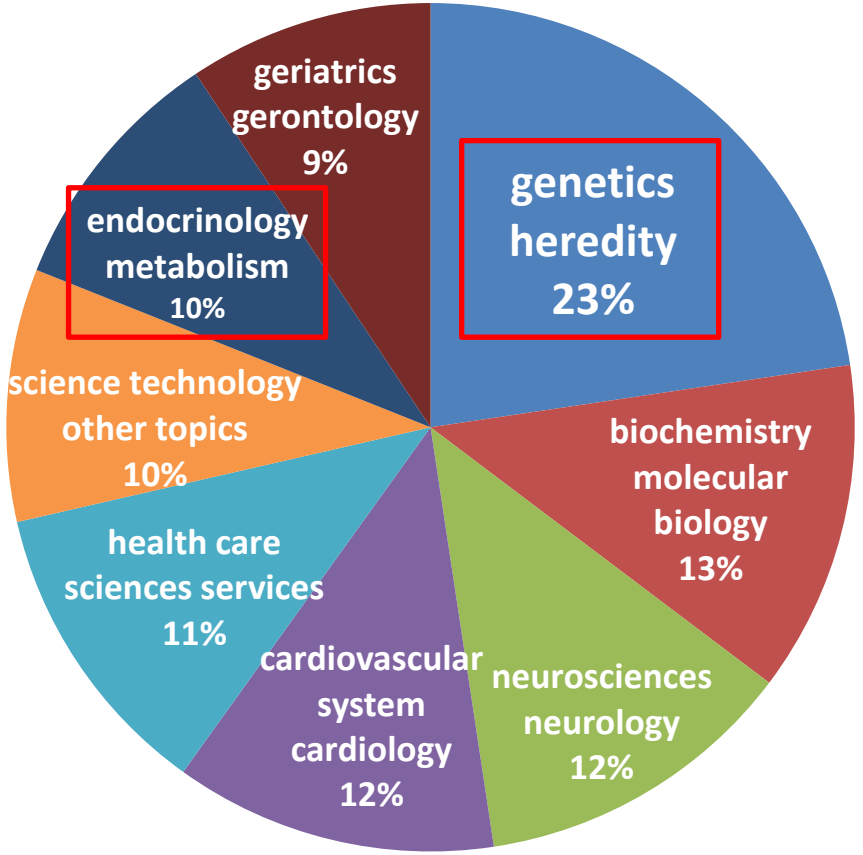


Omics and Multi-Omics| UK Biobank

- A search using "UK Biobank" as the keyword in **Web of Science** reveals a broad range of research fields.
- In the past five years, the proportion of articles related to **omics** has steadily **increased**.



The **First Ten** Years (2002-2011)



The **Past Five** Years (2020-2024)

Omics and Multi-Omics| UK Biobank

nature medicine

Article https://doi.org/10.1038/s41591-024-03142-z

Proteomic signatures improve risk prediction for common and rare diseases

Proteomic-based prediction models → **common and rare diseases** (e.g., multiple myeloma, non-hodgkin lymphoma)

nature

Article | Open access | Published: 04 October 2023

Plasma proteomic associations with genetics and health in the UK Biobank

- Map **genetic associations** for nearly 3,000 proteins.
- Reveal novel insights into the **proteome's genetic architecture** and advanced **drug discovery and disease understanding**.

nature medicine ARTICLES https://doi.org/10.1038/s41591-022-01980-3

Check for updates

OPEN

Metabolomic profiles predict individual multidisease outcomes

NMR-derived metabolomic profiles → **common diseases** (e.g., type 2 diabetes, dementia, and heart failure)

Omics and Multi-Omics| UK Biobank

nature medicine

Article

https://doi.org/10.1038/s41591-024-03142-z

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nature

health in the UK Biobank

- Map genetic associations for nearly 3,000 proteins.

architecture and advanced drug discovery and disease understanding.

Given that single-omics approaches can only study biological systems from one perspective, they often fail to reveal the full functional complexity of an organism

nature medicine

ARTICLES

https://doi.org/10.1038/s41591-022-01980-3

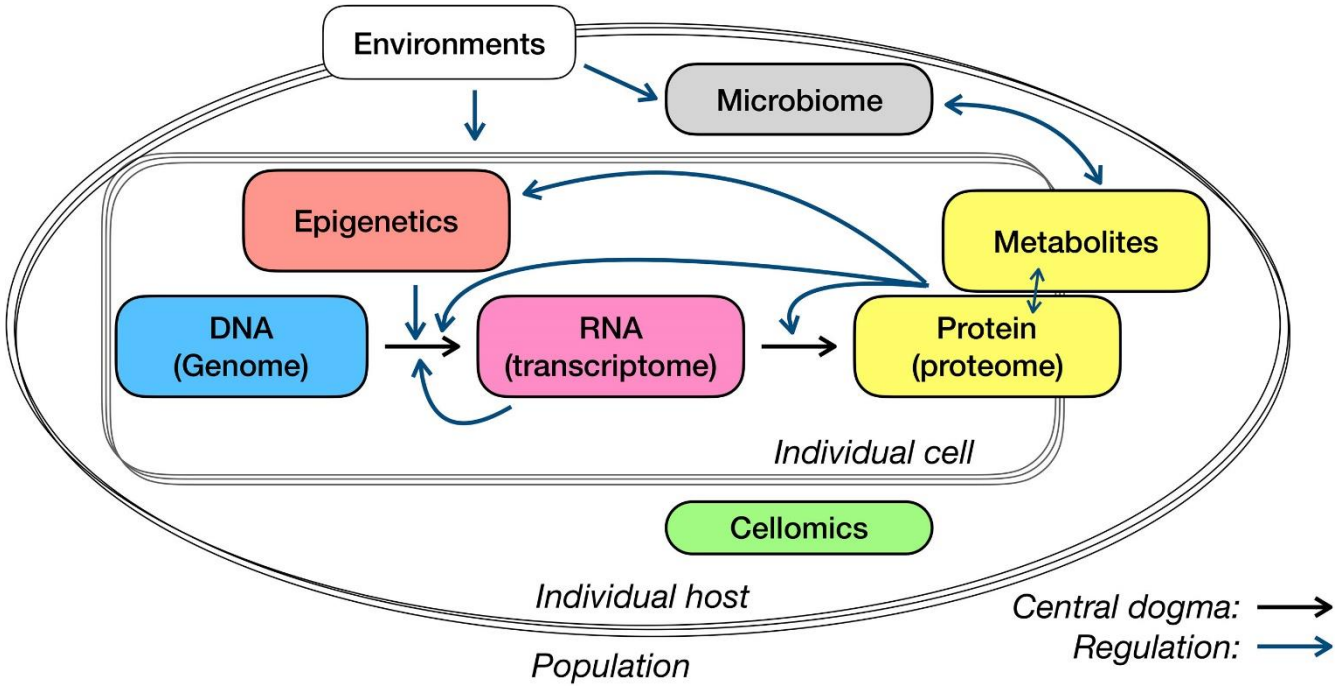
Check for updates

OPEN

Metabolomic profiles predict individual multidisease outcomes

NMR-derived metabolomic profiles → common diseases (e.g., type 2 diabetes, dementia, and heart failure)

Omics and Multi-Omics| Multi-omics

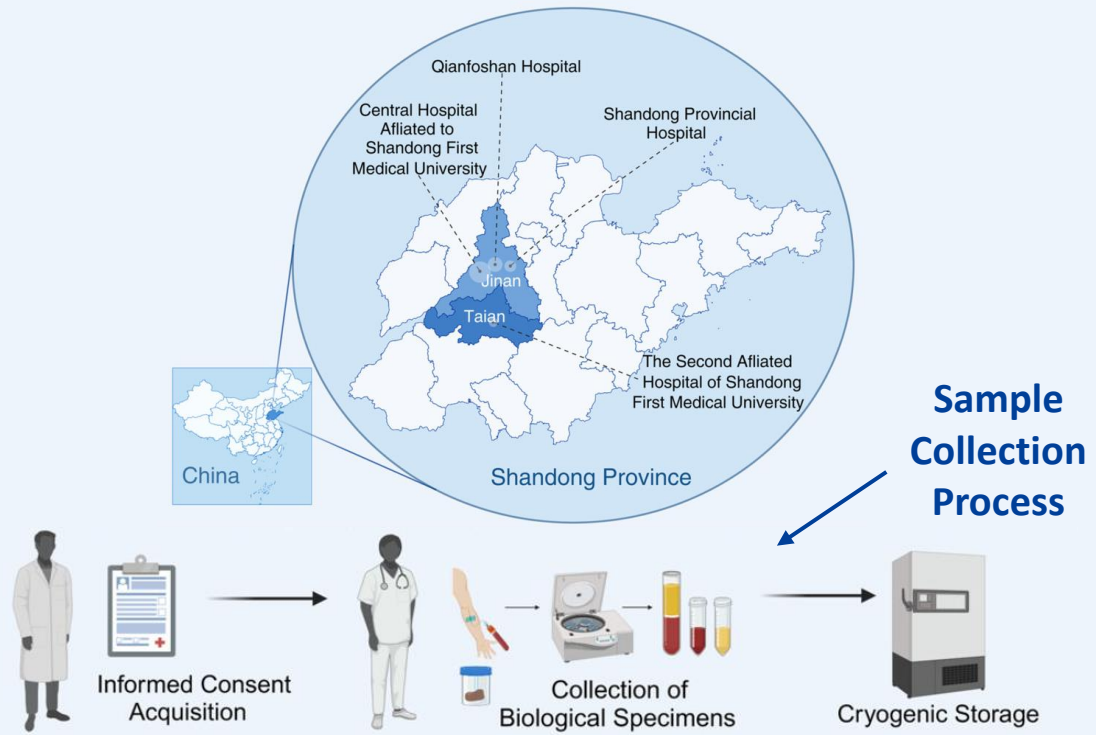


- Multi-omics integrates genomics, transcriptomics, proteomics, and metabolomics to study complex molecular interactions.
- It provides a comprehensive view of how genes, RNA, proteins, and metabolites function under various conditions.

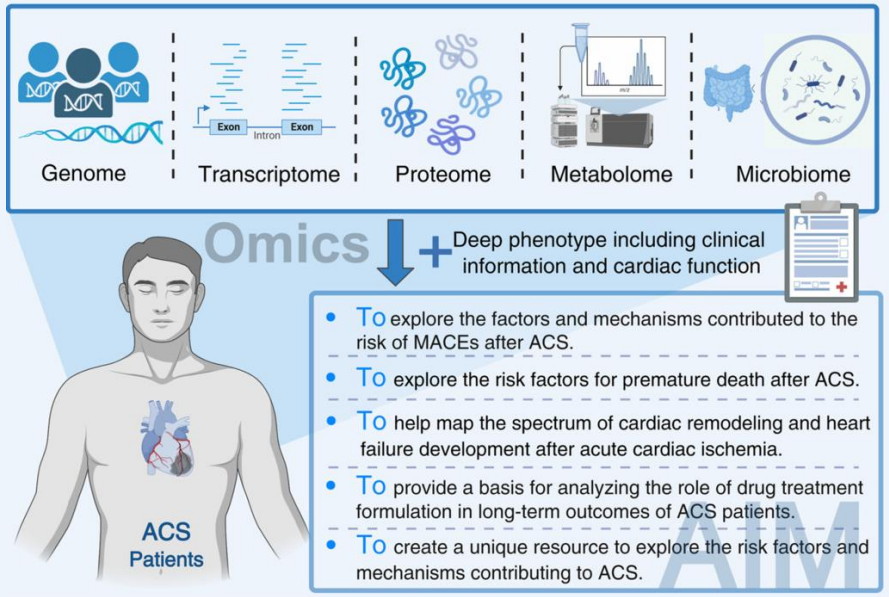
- **Multi-omics analysis integrates data across molecular levels to understand biological systems, uncover therapeutic targets, and support disease prevention, diagnosis, and drug development.**

Front Immunol. *2021;12:668045*

Omics and Multi-Omics| LM-ACS



- **The longitudinal multi-omics cohort of patients with acute coronary syndrome (LM-ACS)** is designed as a real-world prospective cohort of patients with acute coronary syndrome (ACS) requiring coronary angiography.



- LM-ACS generates multi-omics data (**genomics, proteomics, metabolomics, microbiome**) to study ACS etiology and outcomes.
- Multi-omics aims to uncover the etiology of ACS and the process of post-ischemic heart remodeling, advancing **precision medicine**.

https://doi.org/10.1002/imo2.18

Omics and Multi-Omics| Advantages and challenges

Advantages

- **Causal Inference**

  Explores environmental and genetic roles in disease etiology. Reveals molecular mechanisms of complex diseases.

- **Mediation Analysis**

  Identifies pathways linking lifestyle factors to diseases. Provides insights into disease mechanisms.

- **Risk Prediction**

  Develops risk models for precision medicine. Identifies high-risk individuals and optimizes treatment.

Challenges

- **High Costs**

  Lab testing in a large-scale cohort is expensive.

- **Complex Data**

  High variability and multi-factor influences complicate analysis.

- **Ethics and Data Sharing**

  Ethical and data-sharing issues need careful attention. Global collaboration is challenging.

What alternatives / modern methodologies & Why?

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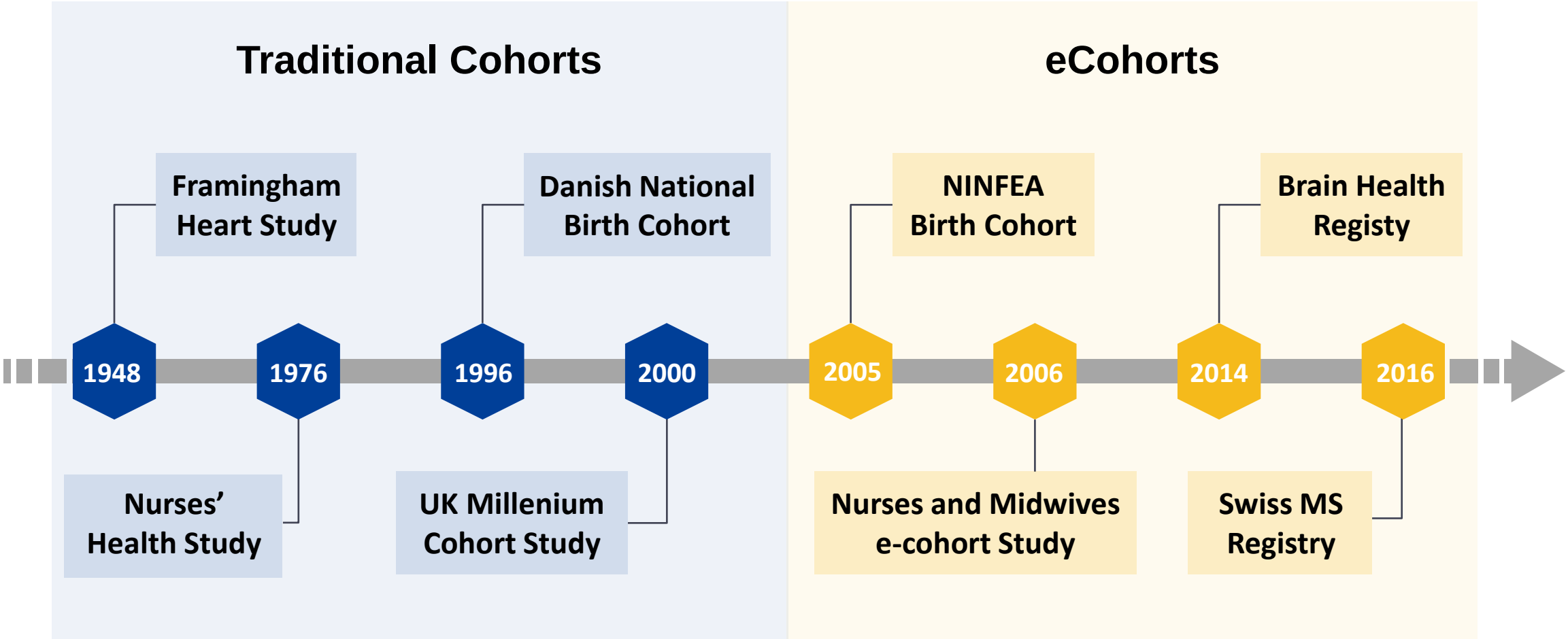
This prolonged follow-up in traditional cohorts increases the need for manpower, time, and financial resources, adding to the complexity and cost of the research.

eCohorts and Remote Data Collection| Overview

- **eCohorts**, also often referred to as online or web-based cohorts, are the inevitable result of recent technological advances as well as societal developments.



eCohorts and Remote Data Collection| Overview

Characteristic	eCohort	Traditional cohort
Sampling	• Nonrandom, self-selected volunteers	• Random or clinic-based
Recruitment	• Primarily online (webpages, social media, etc.) • Electronic consent	• Offline (flyers, in-clinic) • Face-to-face consent
Follow-up	• Primarily online and usually directly reported by participants • Rarely linked to medical care	• Primarily offline • Usually linked to medical care; personal relationship
Analysis	• Self-reported data • Quick access and analysis	• Multiple data streams • Slower analysis process
Dissemination	• Frequent online dissemination • Promotes reproducibility and participant engagement	• Slower publication • Findings used for clinical tools

JMIR Public Health Surveill. *2021;7(1):e24588*

eCohorts and Remote Data Collection| Brain Health Registry

BrainHealth REGISTRY

Alzheimer's Disease

Depression

Parkinson's Disease

Post-Traumatic Stress Disorder (PTSD)

Other Brain Function-Related Conditions

The Brain Health Registry, BHR

- University of California
- An Online, Longitudinal Platform with 100,000+ members

Participation Methods

- 🌐 Remote Recruitment
- 🔍 Internet-based Screening
- 📈 Longitudinal Assessment

Facilitating observational studies & clinical trials through innovative online methods

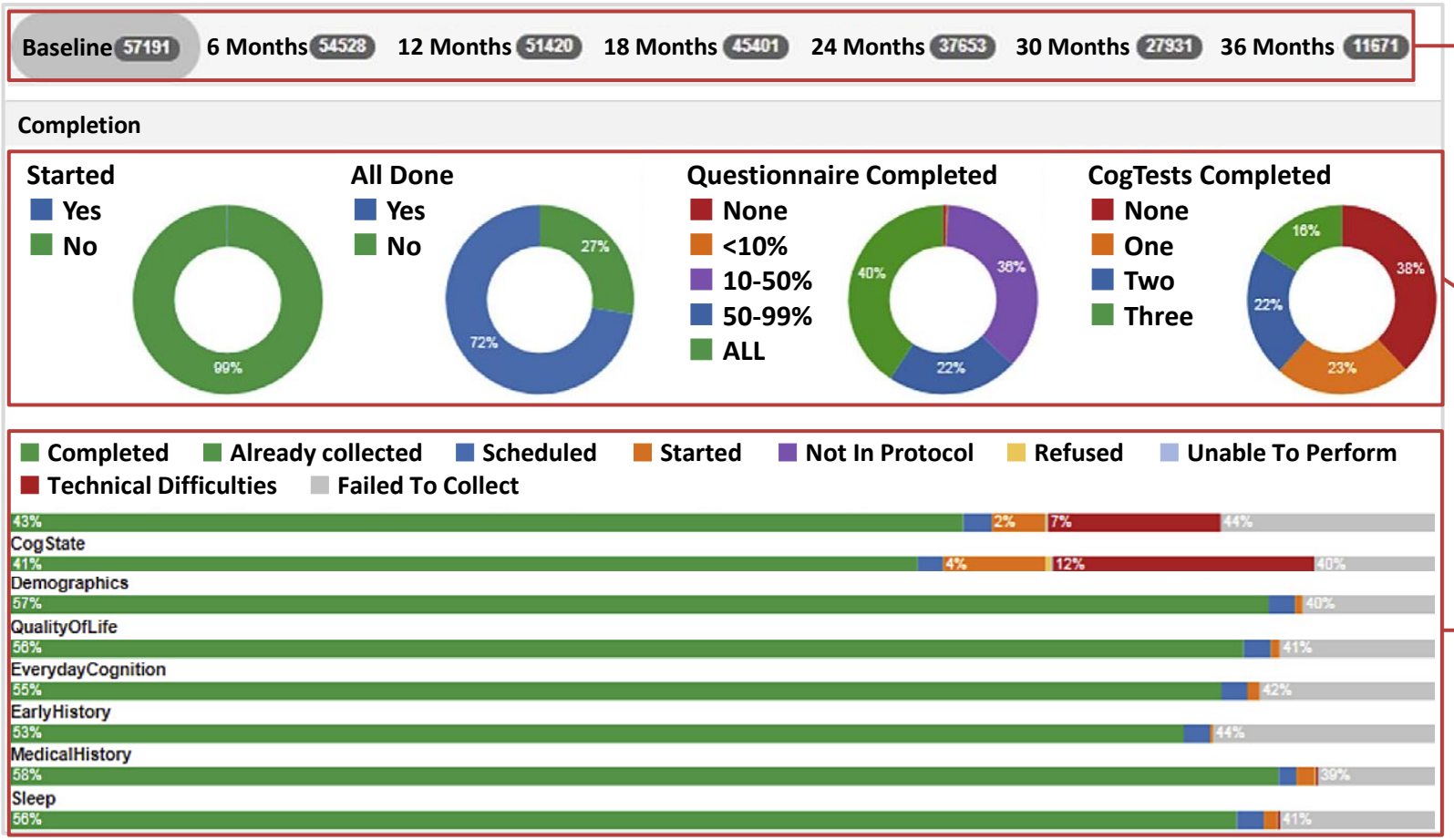
Assessment Methods

- Self-Report Questionnaires
- Study Partner Reports
- Neuropsychological Tests

Comprehensive assessments for accurate tracking & insights.

eCohorts and Remote Data Collection| Brain Health Registry

BHR dashboard offers up-to-date information



Switch between baseline and follow-up visits

Total numbers of consented participants and subtotals of participants who completed questionnaires or tests

Percentage of completed of online questionnaires and each cognitive test

- Over 18,800 participants were referred to, and nearly 1800 were enrolled in clinical Alzheimer's disease and aging studies, including **five observational studies** and **seven intervention trials**.

Alzheimers Dement. *2018;14(8):1063-1076*
Alzheimers Dement. *2023;19(11):4935-4951*

eCohorts and Remote Data Collection| Advantages and challenges

Advantages

- **Large Scale and Breadth**

  eCohorts transcend geographic limits, enabling cross-border studies, regional collaboration, and centralized management.

- **Low Cost**

  Online recruitment and data collection reduce labor and material costs, and extended follow-up lowers overall expenses.

- **Long-term Tracking**

  eCohorts allow extended monitoring of participants' health and life changes, providing valuable data for disease and risk factor research.

Challenges

- **Representativeness**

  Data may not represent the target population, affecting validity, especially for disease risk studies.

- **Privacy and Ethical Risks**

  Online studies carry privacy risks, including potential data misuse or breaches during recruitment and collection.

- **Limited Control over Data Collection**

  Researchers may have little control over data timing and frequency, causing gaps in biological or behavioral data.

What alternatives / modern methodologies & Why?

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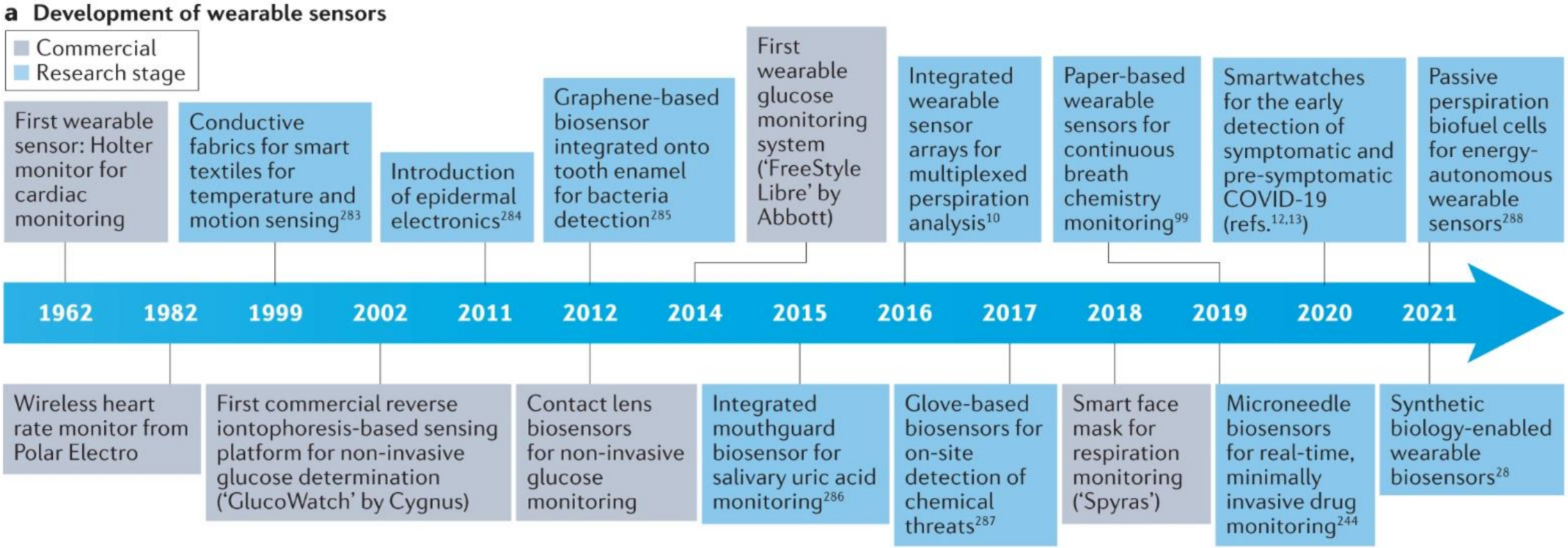
5. A Brief Introduction

Traditional cohorts often collected data at a certain point in time, while **dynamic indicators** (e.g. blood glucose and heart rate) need continuous assessment.

Wearable Devices| Overview



- **Wearable devices** provide an alternative pathway to data collection and clinical diagnostics by exploiting various physical, chemical and biological sensors to mine physiological (biophysical and/or biochemical) information in real time (preferably, continuously) and in a non-invasive or minimally invasive manner.

Nat Rev Mater. *2022;7(11):887-907*

Wearable Devices| ABCD Study

JAMA Network Open

Original Investigation | Psychiatry

Machine Learning–Based Prediction of Attention-Deficit/Hyperactivity Disorder and Sleep Problems With Wearable Data in Children

- **The Adolescent Brain Cognitive Development (ABCD) Study** is the largest long-term study of brain development and child health in the United States.

- The ABCD Research Alliance has enrolled 11,880 children aged 9-10, tracking their biological & behavioral development from adolescence to young adulthood.

- The ABCD study provides wearable data **(Fitbit Wearable Wrist Tracker, Google LLC)** on children's **physical activity, sleep, and heart rates**.

- This data is used to predict and assess early signs of attention-deficit/hyperactivity disorder **(ADHD)** and **sleep problems**.

⇩

- **Limitation**: Wearable data lacks accuracy, making the results better suit for **early detection or screening** rather than **diagnosing** ADHD or sleep problems.

JAMA Netw Open. *2023;6(3):e233502*

Wearable Devices| Application

wrist-worn accelerometers

Go-Pro

Westlake Precision Birth Cohort

Used for **continuous glucose monitoring** and **activity tracking**.

To explore optimal nutrition for GDM patients and the link between personalized glucose responses and birth outcomes.

LifeVest

UK Biobank

Used for tracking brief bursts of **vigorous intermittent lifestyle physical activity** (VILPA) in daily life.

To assess the association between VILPA and mortality rates.

continuous glucose monitoring

Axivity AX3 accelerometer

WEARIT-France cohort

Used for monitoring **nocturnal heart rate changes**.

To predict short-term cardiovascular events and prevent adverse outcomes with real-time data.

Nat Med. *2022 Dec;28(12):2521-2529*
iMeta e2: 96 https://doi.org/10.1002/imt2.96

Wearable Devices| Advantages and challenges

Advantages

- **Real-time data collection**

Real-time health monitoring with instant feedback for proactive prevention and management.

- **Data-Driven Health Insights**

Cloud computing and machine learning offer precise health trends and personalized recommendations.

- **Convenience and Ease of Use**

Continuous health monitoring integrated into daily life, reducing the need for frequent hospital visits.

Challenges

- **Technological Maturity**

Sensors and sampling technologies, like micro-needles, are not yet fully developed for long-term monitoring.

- **Data Privacy and Management**

Managing and securing the vast amount of data generated poses ongoing challenges.

- **Social Acceptance**

Trust and usability, especially among older adults or those without smartphones, remain barriers.

- **Health Inequality**

Risk of widening health disparities if access to wearable technology is limited by socioeconomic factors.

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Integrating diverse data collected in cohort, such as lifestyle, clinical metrics, multi-omics and imaging, is challenging due to the lack of effective methods to analyze thousands of variables, often limiting scientific discovery.

5. A Brief Introduction of the Jiangsu Birth Cohort Study

Artificial Intelligence| iPOP

Dr. Michael Snyder

- **The iPOP (Integrated Personal Omics Profiling) study** is a longitudinal project, profiling around 100 individuals to establish a foundation for **precision medicine** through deep biochemical analysis.

- It collects **multi-omics data**, including genomics, transcriptomics, proteomics, microbiome, and metabolomics, along with **lifestyle and physiological data from wearable devices**, to track health and illness over time.

iPOP

INTEGRATIVE PERSONAL OMICS PROFI

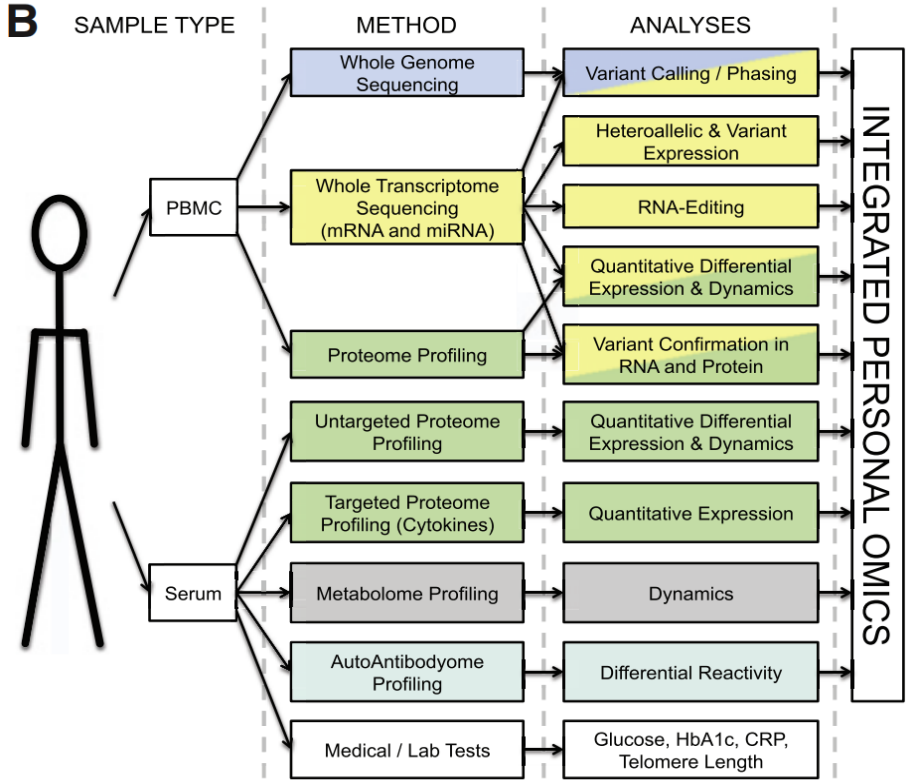
Stanford MEDICINE

The Jackson Laboratory

Leading the search for tomorrow's cures

https://med.stanford.edu/snyderlab/ipop.html

Artificial Intelligence| iPOP



"Personalized medicine is expected to benefit from combining genomic information with regular monitoring of physiological states by multiple high-throughput methods."

Cohort Description

- Participants: 106 individuals (55 females, 51 males)
- Age Range: 25 to 75 years
- Follow-up: Long-term, with quarterly sample collection

Sample Collection

- Types of Samples: Blood, stool, skin, oral, and nasal

Omics Analyses

- Genomics, transcriptomics, proteomics, methylomics, metabolomics, cytokines, microbiome

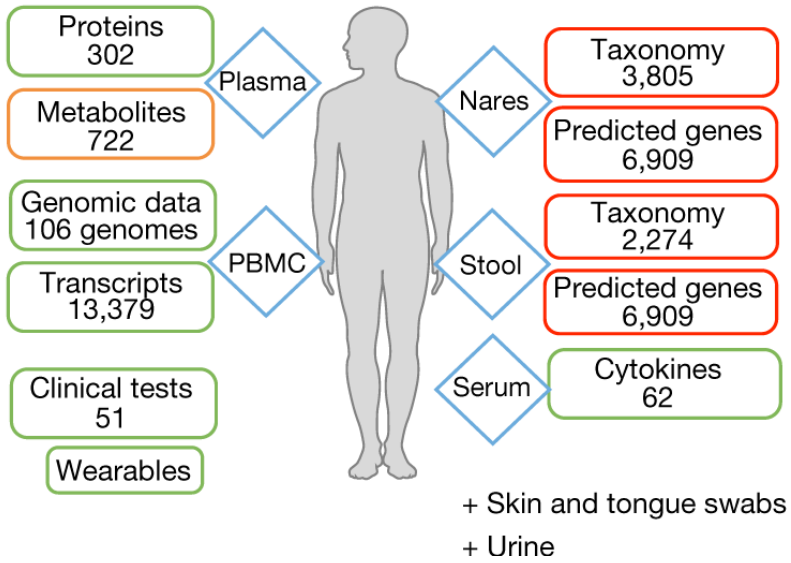
Data Collected

- Lifestyle Factors: Diet, stress, activity levels, personal and family medical history
- Wearable Devices: Physiological and activity data

Cell. *2012;148(6):1293-307*

Artificial Intelligence| iPOP

- **Objective:** This study aims to understand the **early stages of type 2 diabetes (T2D)**, its impact on biological processes, and the transition to clinical T2D through multi-omic profiling of healthy and prediabetic individuals, revealing early molecular signatures.
- **Data Collection:**



- **Use of Machine Learning:**

Logistic Regression **Support Vector Machine**

I. **Classification Models:** Used to differentiate between various stress events

II. **Key Feature Selection:** Identified key predictive features to distinguish stress from healthy states.

III. **Data Processing and Validation:** Employed scikit-learn for model implementation, using L1 regularization and cross-validation for optimization.

- **Findings:** Overall, this study reveals the complex multi-omic landscape of healthy individuals and those with insulin resistance under stress, providing new insights into the **early molecular mechanisms of T2D**.

Nature. *2019;569(7758):663-671*

Artificial Intelligence| Advantages and challenges

Advantages

- **Powerful Research Tools**

Analyze large datasets, identify patterns, generate hypotheses, automate repetitive tasks, and assist with literature

- **Personalized Medicine**

AI enables the development of personalized treatment plans based on individual patient data.

- **Predictive Analytics**

AI can analyze vast amounts of data to predict disease onset and progression, leading to early intervention.

Challenges

- **Technical and Implementation Issues**

High costs and technical constraints hinder data collection and AI deployment.

- **Management and Security Difficulties**

Managing and securing the vast amount of data generated poses ongoing challenges.

- **Trust and Explainability**

AI systems often function as “black boxes,” complicating understanding of their decision-making.

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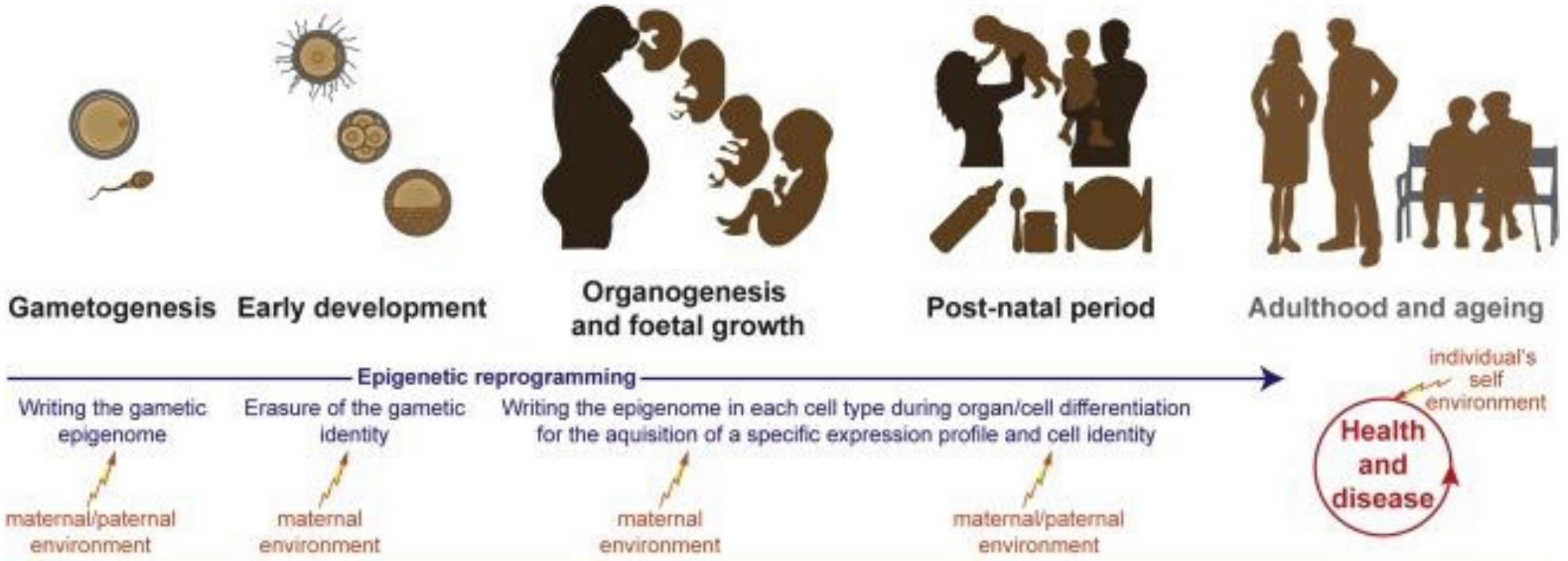
5. **A Brief Introduction of the Jiangsu Birth Cohort Study**

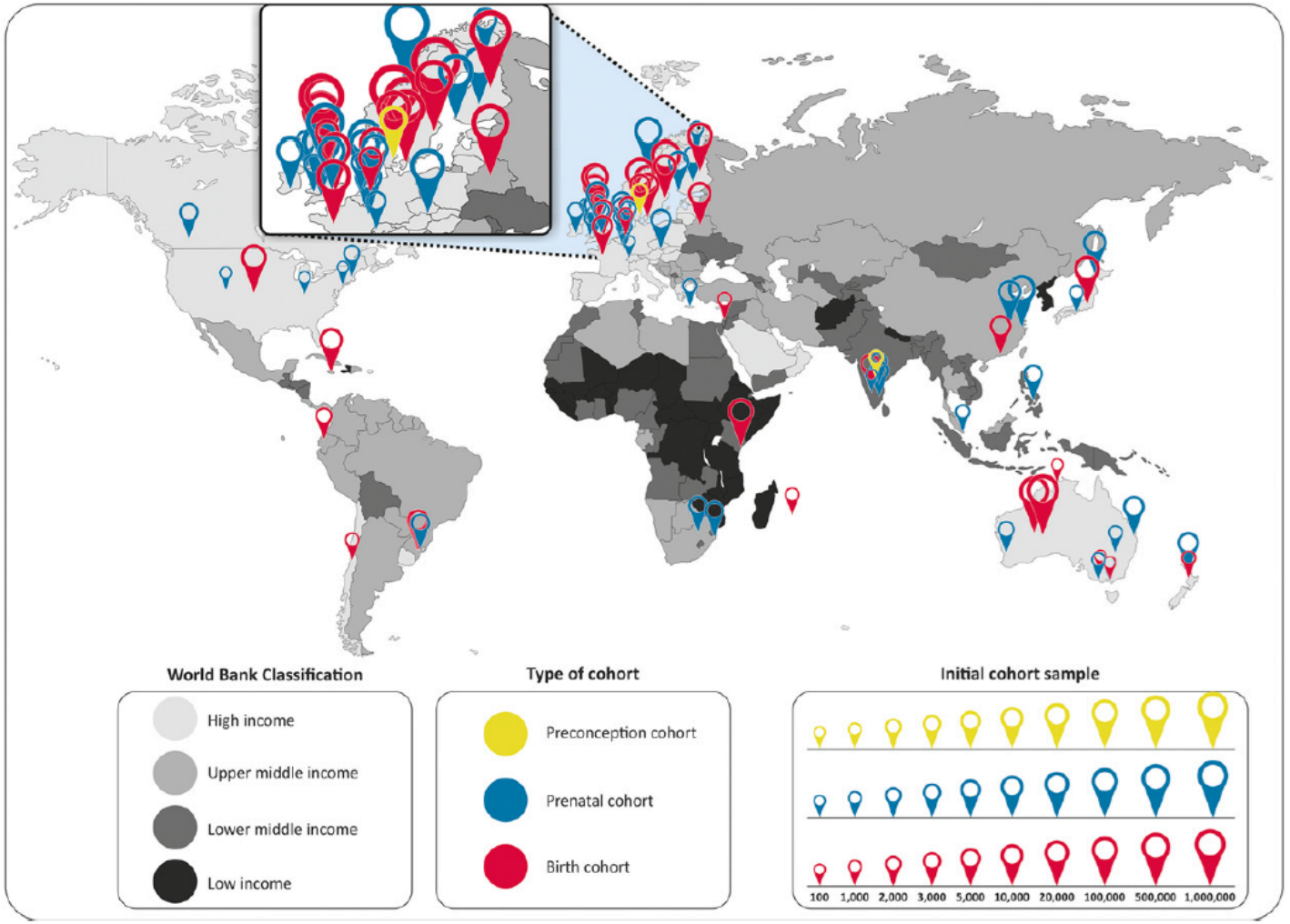
Significance of Birth Cohort

- Developmental Origins of Health and Disease (DOHaD)
- Increasing evidence on the long-lasting effects of preconceptional exposures
- Birth cohort is the "**natural experiments**" to test the DOHaD theory



Nature. *2014;507(7490):22-4*

Map of the location of birth cohorts

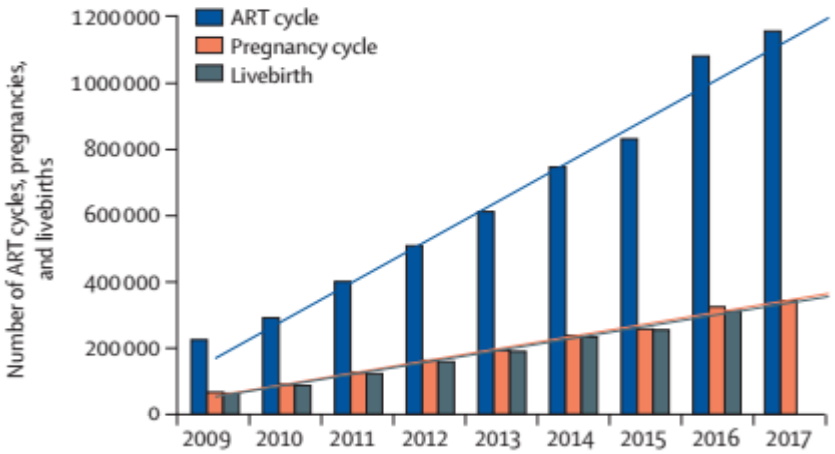


Map of the location of world preconception, prenatal, and birth cohorts

Neoreviews. 2018 19(6): e313-e321

Wide Use of Assisted Reproductive Technology

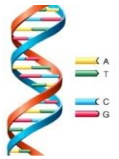
- The first test-tube baby was born in the UK in 1978, in China in 1988
- More than 10 million ART births worldwide
- Three of per 100 babies are born after ART in China



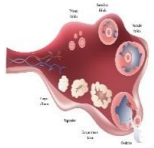
Paternal origin
Maternal origin

Potential adverse exposure in the implementation of ART

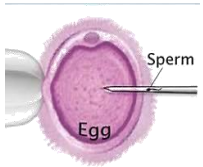
Infertility factors → **Exogenous hormones** → **Micromanipulation Chemical reagent** → **Luteum support Extra prenatal testing**



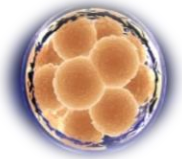
Gamete information Epigenetic modification



Promote ovulation



ICSI



Embryo

Fetus

Newborn

Long-term

The short- and long-term health of children born via ART warrants comprehensive evaluation.

Science. *2014*
Nature. *2014*

The Jiangsu Birth Cohort

36,000 families | **Trios** design | **>80%** follow-up rate

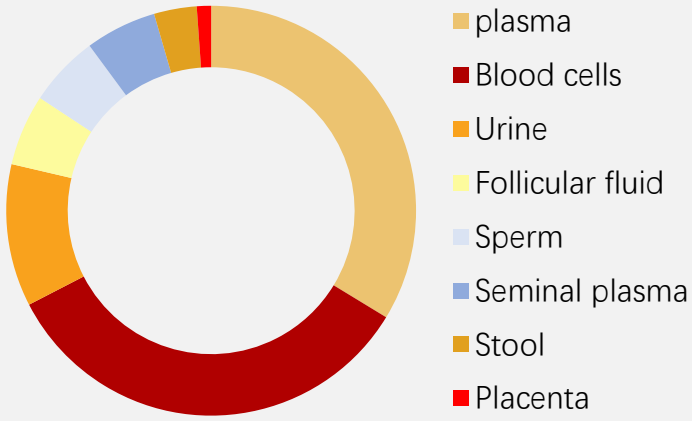
ART couples
NC couples

Pre-pregnancy → Early-pregnancy → Mid-pregnancy → Late-pregnancy → Birth → 42 day after birth → 6m after birth → 1 year → 3 years → 7 years

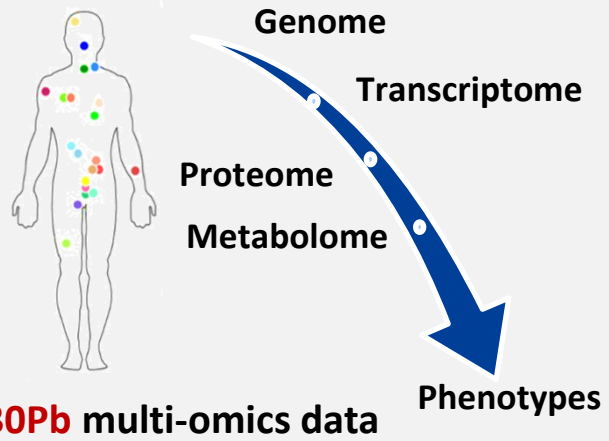
Billions of information

- Environmental exposure
- Life-styles
- Clinical data
- ....

Millions of bio-samples



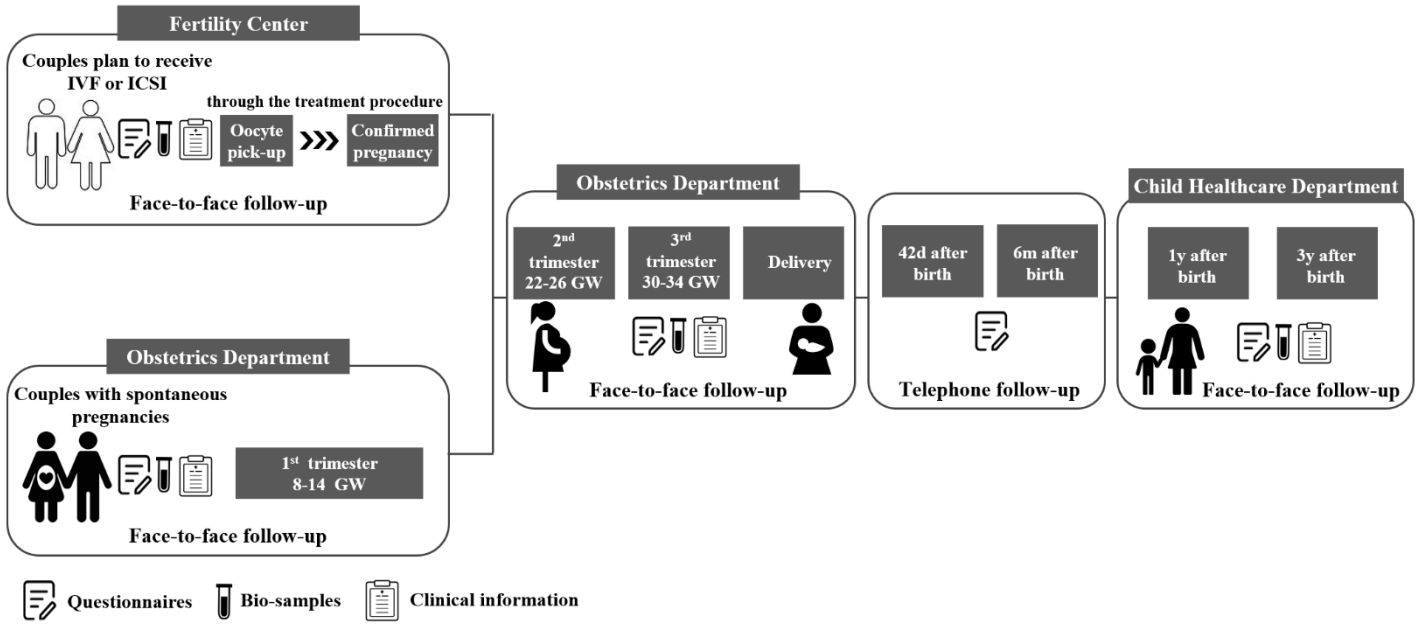
10 thousand family-based molecular profiles



30Pb multi-omics data

Supporting research on reproductive and offspring health

The Jiangsu Birth Cohort



"The overarching goals of the JBC were to systematically assess the health and wellbeing among children conceived using ART as compared with those who were conceived spontaneously, and to clarify whether the elevated risks are attributable to parental characteristics related to infertility or to ART procedures, taking into consideration ART-related parental characteristics. "

Int J Epidemiol. 2023

International Journal of Epidemiology, 2023, 00, 1–10
https://doi.org/10.1093/ije/dyad139
Cohort Profile

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Cohort Profile

Cohort Profile: The Jiangsu Birth Cohort

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The members of the collaborative group of the China National Birth Cohort are listed in the Acknowledgements section.

Key Features

- The Jiangsu Birth Cohort (JBC) is a family-based prospective cohort in Jiangsu Province, China, consisting of families receiving assisted reproductive technology (ART) treatment or families with spontaneous pregnancies. The study aimed to investigate the differences between the two groups of participants regarding both short- and long-term health outcomes in women and their offspring.
- The cohort recruited couples who planned to receive ART treatment at ART clinics, and collected data on the ART procedures and outcomes. Spontaneously conceiving couples were recruited during early pregnancy (8–14 weeks of gestation) at obstetrics clinics. Thereafter, ART pregnancies and spontaneous pregnancies were followed throughout the whole gestation with the same protocol. After childbirth, all children were followed until up to 3 years of age.
- Data on health were collected through standardized and structured questionnaires and medical records, together with biospecimens from both parents and their children. The cohort thus provided a valuable resource for the research on parental and child health associated with ART pregnancies.
- Between April 2014 and June 2022, the JBC has recruited 7618 ART treated families and 14 996 families of spontaneous completed or ongoing pregnancies. For the families enrolled up to 30 June 2020 (5061 ART families and 12 793 spontaneous conception families), we have completed data from their entry throughout their fertility care (for ART families), pregnancy, birth and 1 year after childbirth when child health was evaluated by the health examination.
- Data are hosted in the China National Birth Cohort (CNBC) study group and data access may be granted via an enquiry to [cnbc@njmu.edu.cn].

Why was the cohort set up?

Following the success of the first test-tube baby in the UK in 1978, the use of assisted reproductive technology for infertility treatment has increased steadily and resulted in more than 9 million children born after assisted reproductive technology (ART) worldwide.[1,2] In China, approximately 15–25% of couples suffer infertility.[3] Consequently, ART has become a standard and common practice in reproductive medicine clinics, and more than 1.6% of children in China are conceived through ART.[4] Meanwhile, concerns are mounting over the safety of ART and its short- and long-term health impacts on maternal and fetal wellbeing. Emerging data from some, though not all, studies suggest that compared with spontaneous pregnancies, offspring conceived through ART are prone to adverse perinatal outcomes such as preterm birth, low birthweight, small size for gestational age and perinatal death.[5–7] Further, offspring conceived through ART were reported to have an elevated risk of multiple diseases such as congenital heart defect, impaired vascular function, metabolic syndromes and cancer.[8–13] Whether the elevated risks are attributable to parental characteristics related to infertility or to ART procedures warrants elucidation.

Received: 29 November 2022. Editorial Decision: 14 September 2023Accepted: 28 September 2023

The Jiangsu Birth Cohort

研究进展

- Cell Reports： 多组学图谱揭示心脏发育过程关键分子开关
- Nature Medicine：经囊胚期移植的辅助生殖子代的白细胞端粒长度
- Cell Res：揭秘辅助生殖与后代先心病的关系！南京医科大团队发现，新生突变增加是辅助生殖子代先心病风险升.
- The Lancet Regional Health-Western Pacific：辅助生殖技术安全性评估需重视子代的近远期健康
- Sci Total Environ：产前PM2.5暴露与11-12.5月龄神经发育的关联研究
- Am J Obstet Gynecol：产前皮质类固醇与子代神经发育的关联研究
- Nutrients: 妊娠期母亲膳食模式与子代神经发育的关联研究
- BMC Pregnancy Childbirth：Stress, anxiety, and depression in infertile couples are not associated with a f
- 中华流行病学杂志：中国国家出生队列母婴肠道微生物亚队列研究

The Jiangsu Birth Cohort

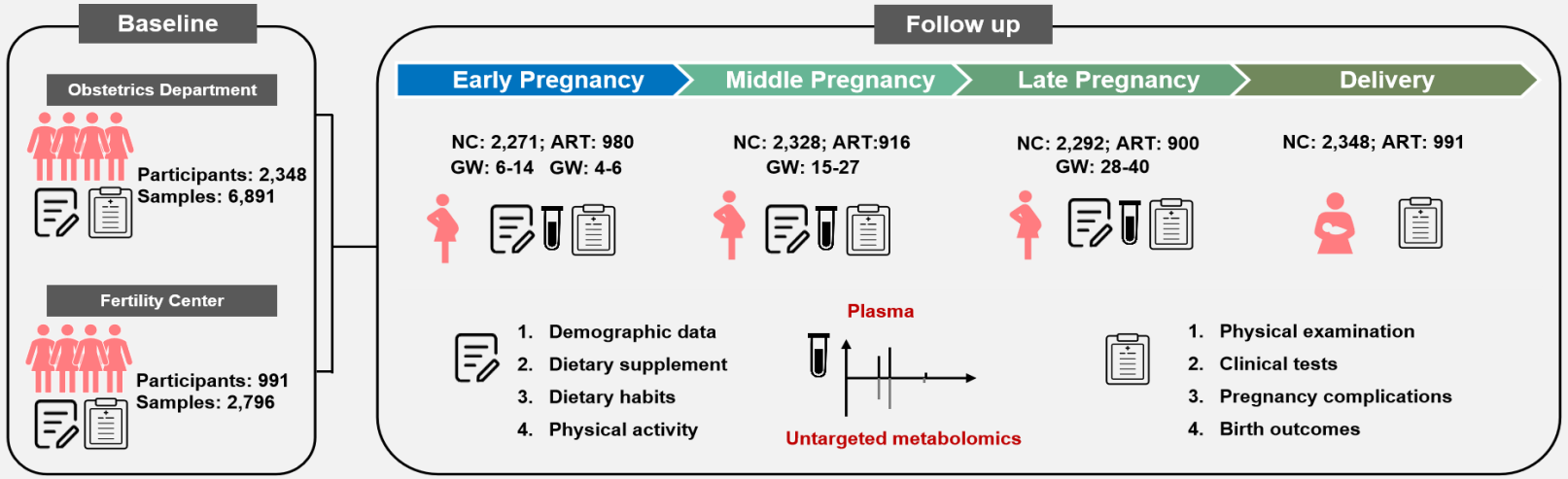
The follow-up of school-aged children

Welfare card for cohort children

Follow-up of children at the physical examination center

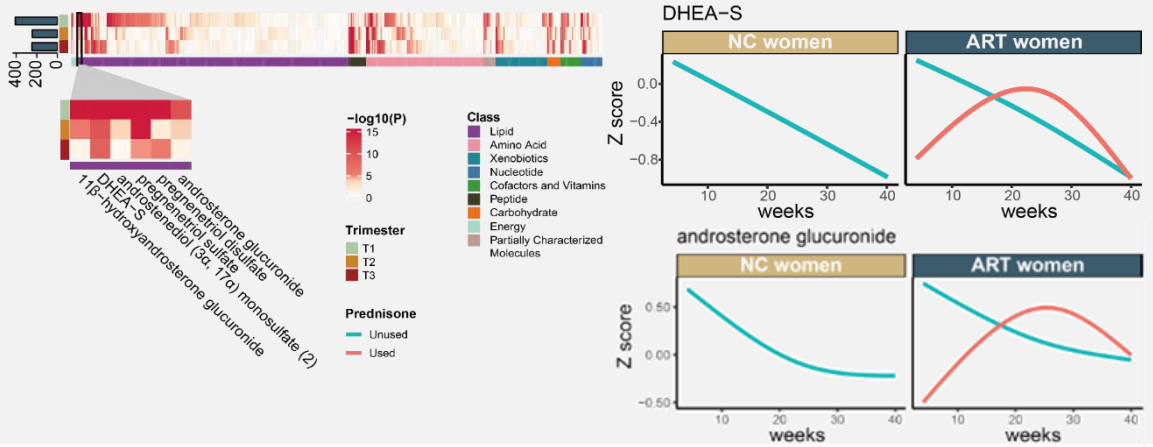
‘omics’ Studies in the Jiangsu Birth Cohort

a metabolome atlas across gestation in human



- Construction of a comprehensive view of the metabolome trajectories throughout pregnancy
- Gain insights on how maternal metabolomic signatures influence maternal and child health outcomes

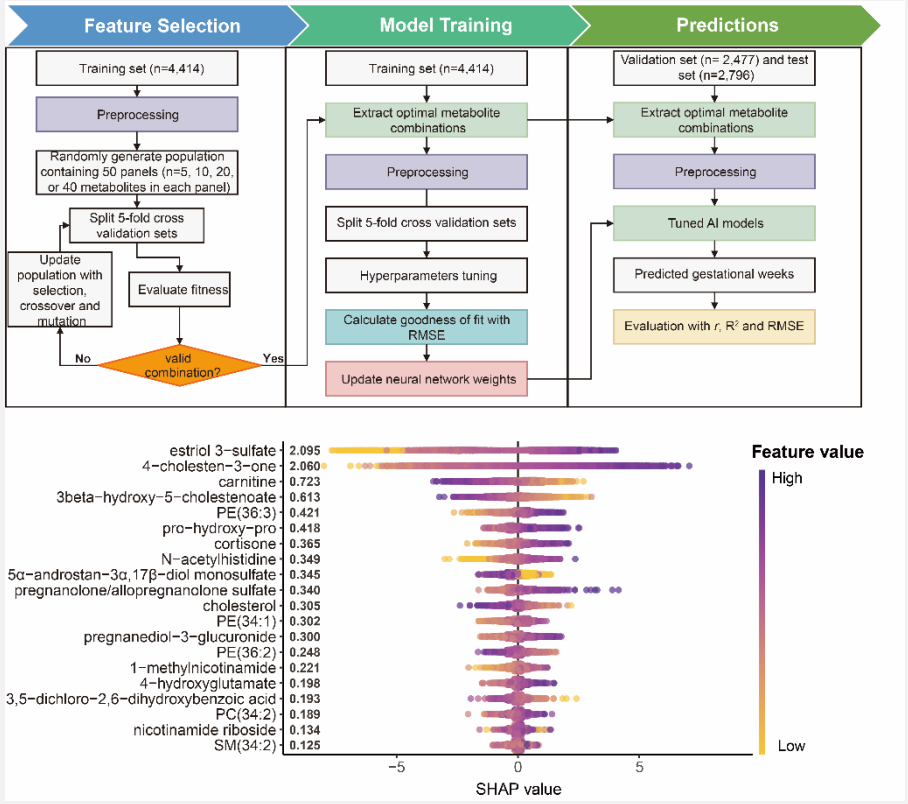
- The metabolic variation during pregnancy is largely consistent between natural and ART pregnancies.
- Prednisone use in ART women in early pregnancy alters the metabolism of steroid hormones, and the impact persists across the whole pregnancy

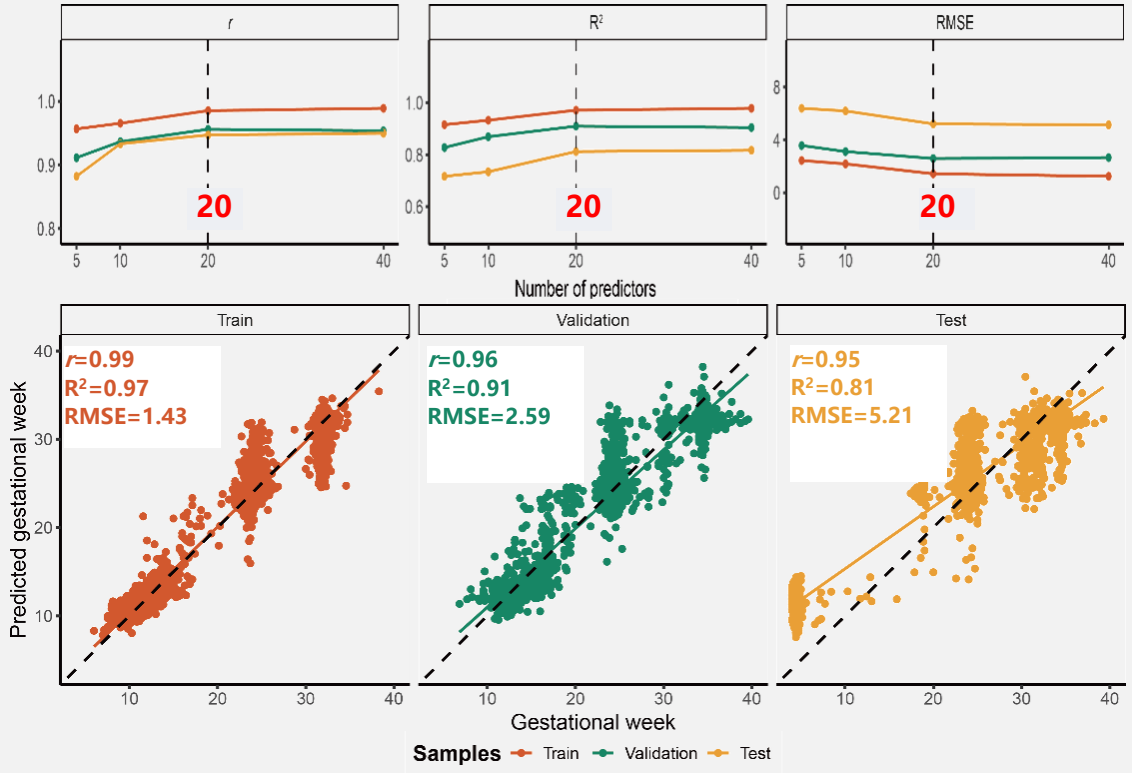


Unpublished data

Artificial Intelligence & Prediction Model

Development of a neural network model for gestational week prediction





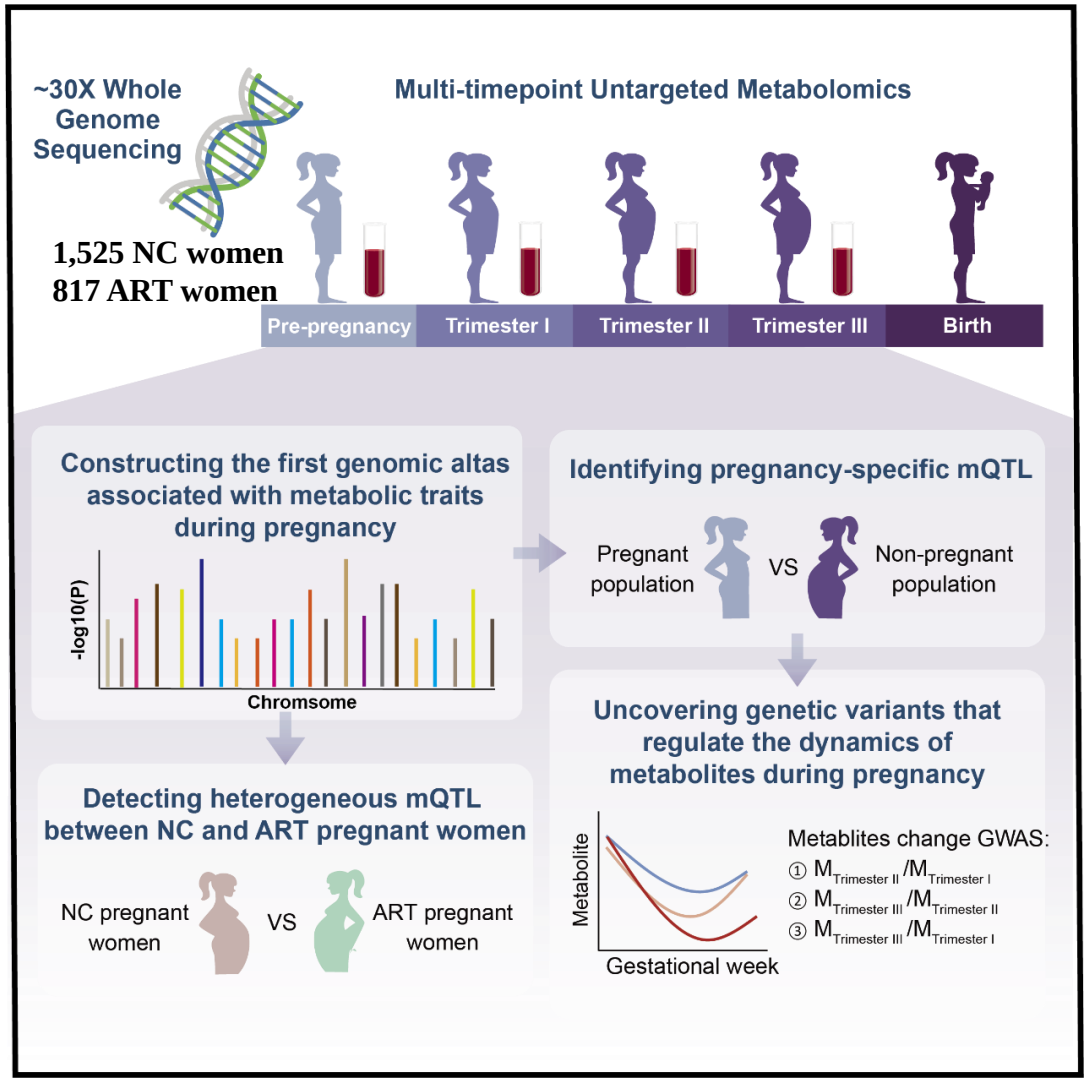
A model of 20 metabolic small molecules, including estriol-3-sulfate, corticosterone and carnitine, can predict gestational age with superior precision, including those conceived after ART and those with pregnancy complications.

Unpublished data

‘Multi-Omics’- Genetics integrated with Metabolomics

- 1,064 independent variant-metabolite associations for 401 maternal metabolites
- 36 pregnancy-specific associations
- Certain variant-metabolite associations were specific to NC or ART population, partially attributable to different physical conditions or clinical interventions

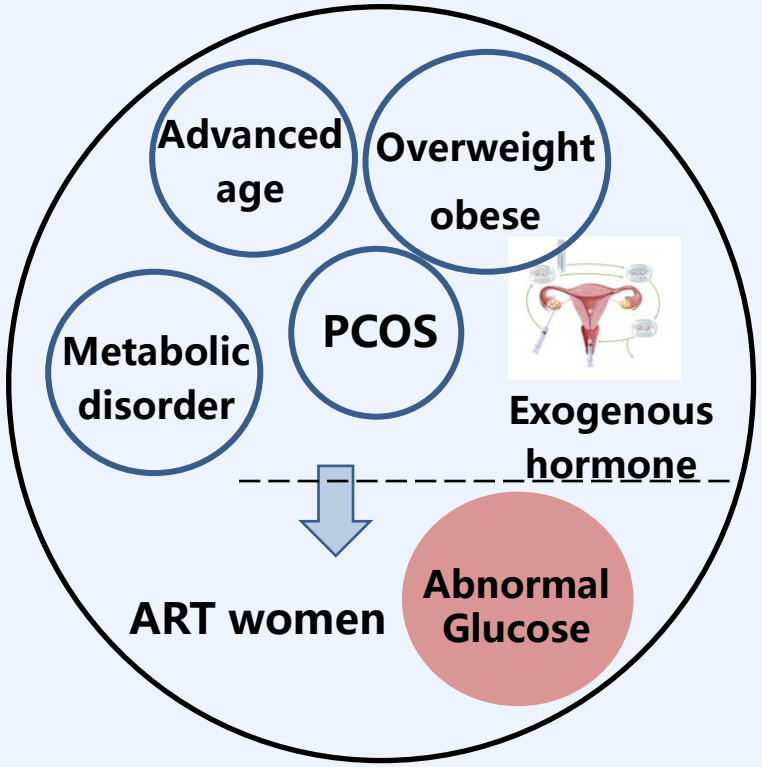
These findings comprehend the genetic regulation of pregnancy metabolism and pinpoint metabolites and genes playing critical roles in pregnancy, offering insights on future strategies in personalized prenatal care.

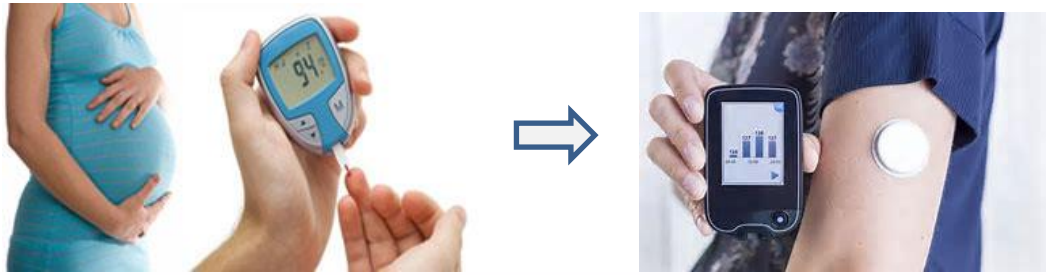


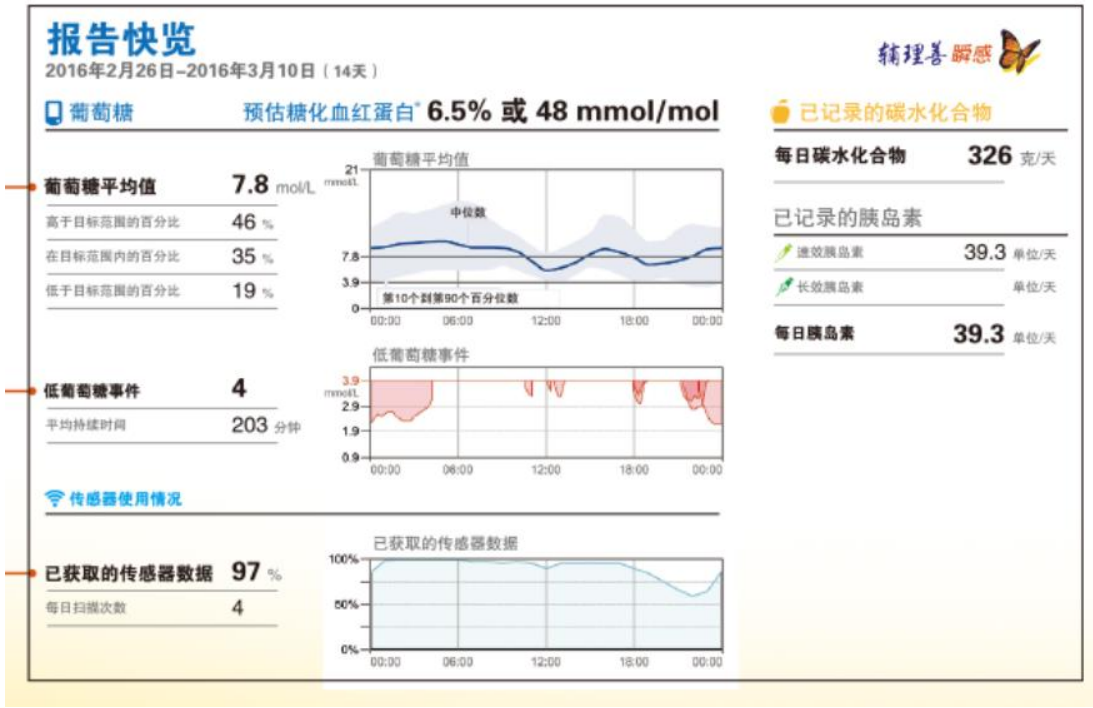
Unpublished data

Wearable Devices| Continuous glucose monitoring in pregnant women

- ART women are susceptible to abnormal glucose during pregnancy







Continuous glucose monitoring to clarify the influence of glucose trajectory on pregnancy outcomes, and to determine the optimal plasma glucose level for ART women.

Summary

- Omics and Multi-Omics— **Interpret Mechanism**
- eCohorts and Remote Data Collection— **Enlarge Scale and Breadth**
- Wearable Devices— **Monitor Real-time Health**
- Artificial Intelligence— **Analyze Complex Data**

Conception innovation, scientific and technology improvement and infrastructure supporting will further promote alternatives and modern methodologies in cohort studies

The JBC research team

Thanks for your attention!