

Improving Adherence

A combination of adherence counseling, tools, and enhanced support strategies can be used to strengthen product adherence in HIV biomedical research clinical trials.

Basic Adherence Strategies

- Counseling strategies include brief one-on-one adherence counseling through problem solving or motivational interviewing approaches.
- Support tools include pillboxes, electronic reminders, and interactive short message service text messages.
- Appointment support strategies include appointment stipends, appointment reminders, and collecting extensive contact information from participants.

Enhanced Adherence Strategies

- Monitoring of adherence through electronic devices, remote sensors, or drug level monitoring, paired with the provision of adherence feedback to participants.
- Psychosocial support to participants including provision of sexual and reproductive health services, or facilitated connections to case management or other needed services.
- Appointment attendance support includes use of community-based outreach teams and expanded evening and weekend hours at a research study site.

Take Home Messages

- Adherence is strongly associated with efficacy and outcomes.
- Reliable and valid adherence assessments are essential for appropriately interpreting trial results.
- Adherence measurement approaches have strengths and weaknesses. Multi-method approaches and triangulation of findings are recommended.
- Product adherence is influenced by product regimen and attributes, participant characteristics, life context, study design, and research site characteristics.
- Design of adherence assessment and support should begin with a theory and evidence-based bio-psychosocial model of factors that contribute to adherence.
- Supporting product adherence in HIV biomedical clinical research involves provision of basic adherence counseling and support tools, as well as enhanced adherence monitoring and support strategies.
- Adherence assessment and support costs must be built into trial protocols and budgets. While these costs may be significant, the cost of failing to appropriately measure and support adherence is far higher.

For questions or comments, please email the NIAID NIMH Behavioral and Social Sciences Project Team at NIAIDNIMHBSSPT@mail.nih.gov.



Strengthening Adherence in HIV Biomedical Clinical Research

Images on front (clockwise from top left): 1) rectal microbicide applicator kit; 2) dried blood spot collection kit; 3) female condoms; 4) intravenous administration; 5) PrEP; 6) pill organizer; 7) vaccine; 8) male condom; 9) Proteus digital pills system; 10) vaginal microbicide products; 11) Wisepill electronic drug monitor; and, 12) vaginal ring.



<https://daidslearningportal.niaid.nih.gov/local/pages/?id=8>

About Adherence

This brochure describes the importance of assessing, supporting, and improving adherence in HIV biomedical clinical research to support efforts in evaluating product safety, acceptability, and efficacy.

- Adherence applies to the use of HIV drug regimens including oral medications, injectable long-acting drugs, infusions of broadly neutralizing monoclonal antibodies, multidose vaccine administration schedules, topical gels, and vaginal rings.
- Adherence is multidimensional. It includes how well participants attend research study visits and follow recommended study product regimens over time.

Importance of Adherence

It is important that participants in HIV biomedical clinical research use study products according to the study protocol for several reasons.

- Incomplete use of study product regimens may prevent detection of therapeutic effect, result in inaccurate dosing recommendations or mischaracterize the product's safety profile.
- Increased study costs may be incurred if additional participants must be enrolled to make up for participants who had low product use or dropped out of the study.
- Non-adherence may be linked to important factors that need to be examined to inform product development and participant recruitment and retention support.

Influences on Adherence

Multiple factors influence adherence to study products, prescribed regimens, and study visits in HIV biomedical clinical research.

- Product regimen and attributes can impact how acceptable, preferable, tolerable and convenient the study products are.
- Study characteristics, such as visit frequency, product intensity, invasiveness, and risks and benefits may influence adherence.
- Participant characteristics that may affect adherence include gender, socio-demographics, health beliefs, literacy, and mental health status.
- Social and structural influences such as HIV-related stigma and mistrust of researchers or researchers may impact adherence.

Assessing Adherence

There is no gold standard method for adherence assessment. All product measurement approaches have strengths (+) and weaknesses (-). Multimethod approaches and triangulation of findings are recommended. Adherence assessment approaches are continually evolving, resulting in changes in precision, cost, and complexity. For a more complete list of adherence measures and their associated strengths and weaknesses, see the Points to Consider document on our website.

