Health Decisions

*Women's health*

# Capabilities for Clinical Studies in Osteoporosis

## Effective Osteoporosis Treatments Are Available but Patient Nonadherence is High

It is estimated that more than 200 million people worldwide suffer from osteoporosis and that approximately 80% of these are women, including approximately 30% of all postmenopausal women.[1] Osteoporosis patients are at high risk of fragility fractures, often with significant or even catastrophic consequences for their health. There are effective therapeutics for osteoporosis in classes that include bisphosphonates, hormonal products, parathyroid hormone, osteoclast inhibitors and selective estrogen receptor modulators (SERMs). However, patient nonadherence with these therapeutics is a major problem, with side effects responsible for the failure of many patients to continue treatment for the prescribed period. For example, rates of discontinuation of treatment exceed 75% for daily regimens of bisphosphonates within the first year and 25% for teriparatide treatment after 18 months.[2,3] Thus, there is a need for new treatments that increase the likelihood of patient adherence.

## Operational and Methodological Considerations in Osteoporosis Trials

Osteoporosis studies involve unique operational and methodological considerations as well as considerations shared with studies in other postmenopausal indications. Such considerations include:

- Patient nonadherence with dosing
- Patient discontinuation because of side effects or lack of perceived benefit from the investigational product
- Variability in DXA (Dual-energy X-ray Absorptiometry) imaging for bone mineral density
- The need to identify sites with appropriate and properly calibrated DXA systems and adherence to daily quality assurance measures
- The need to ensure that sites have International Society for Clinical Densitometry (ISCD)-certified DXA technicians (primary and backup) assigned to the study
- The need to ensure that sites have experience with Vertebral Fracture Assessment (VFA) and Fracture Risk Assessment Tool (FRAX) calculations

> *"...there is a need for new treatments that increase the likelihood of patient adherence."*


1 International Osteoporosis Foundation – Epidemiology. Available from: https://www.iofbonehealth.org/epidemiology

2 Asafo-Adjei TA, Chen AJ, Najarzadeh A, Puleo DA. Advances in Controlled Drug Delivery for Treatment of Osteoporosis. Curr Osteoporos Rep. 2016 October; 14(5): 226–238.

3 Mulgund M, Beattie KA, Wong AKO, Papaioannou A, Adachi JD. Assessing adherence to teriparatide therapy, causes of nonadherence and effect of adherence on bone mineral density measurements in osteoporotic patients at high risk for fracture. Ther Adv Musculoskel Dis (2009) 1(1) 5-11.

- Investigator selection based on treatment of osteoporosis patients by different types of physicians including OB/GYNs, primary care physicians and rheumatologists
- The need for extensive site training and clear communication to site staff and patients about study procedures and obligations.

# Key Risks and Mitigations in Osteoporosis Studies

## Risk 1: Variability in DXA scans

**Mitigations**

- Restrict participation in a study to sites that have prior experience conducting DXA scans in osteoporosis trials
- Require documentation before and during the study that sites consistently perform quality assessment procedures
- Partner with an imaging provider with extensive experience participating in clinical trials involving DXA scans
- Meet regularly with the imaging vendor to review trends and issues and agree on action plans for any delinquent sites.

## Risk 2: Patient nonadherence with dosing, especially with products that require frequent administration under specific conditions

**Mitigations**

- Ensure rigorous patient education about dosing instructions
- Provide patients with informational materials for sites to review with patients about the seriousness of osteoporosis and the importance of being treated
- Provide patients information on what they can expect after starting the investigational product, including potential side effects and the likelihood that benefits will be gradual and perhaps imperceptible
- Implement an electronic drug adherence monitoring program that provides a reminder to take the investigational product
- Require patients to maintain a diary verifying dosing
- Program the electronic drug compliance system to send an automatic alert to the study coordinator if the patient does not enter data in the diary on schedule
- Encourage sites to allocate sufficient time for each patient visit to nurture their relationship with the patient.

# For Assistance With Your Osteoporosis Program

Osteoporosis affects millions of postmenopausal women, posing serious health risks and compromising quality of life. As a CRO committed to improving healthcare outcomes for women, Health Decisions is determined to advance and accelerate clinical development of improved treatments for osteoporosis. In addition, the Health Decisions clinical team understands how to address key operational issues and mitigate risks in osteoporosis trials. Please contact us to explore how Health Decisions can assist with efficient, timely development of your investigational product for treatment of osteoporosis.

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Health Decisions is a full-service CRO specializing in clinical development of drugs, diagnostics, medical devices and combination drug/devices in all areas of women's health as well development of diagnostics for all therapeutic areas. Our experience, expertise, site network and KOL and investigator relationships enable us to address the challenges of developing women's health products in areas including general gynecology indications, contraception, sexual health, infertility, obstetrics, menopause and osteoporosis and other indications that affect women disproportionately and profoundly, including autoimmune disorders and male-factor infertility. Health Decisions is headquartered in Durham, NC.

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