Navigating the Registry-Specific Approval Process for a Long-Term Drug Safety Study

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ABSTRACT
Background: The Forteo Patient Registry (FPR) was established in 2009 to link registry data, study data patients taking teriparatide who voluntarily enrolled in the Registry are participating. Mammography, however, is not performed annually to determine the presence of osteosarcoma.

Objectives: To describe the variation of state cancer registries required for participation in this linkage study and to provide a summary of the first three annual data linkages.

Methods: Cancer registries in all 50 states and the District of Columbia were invited in May 2010 to participate in the first annual linkage. This invitation included all state cancer registries, whether or not they had participated previously. Additional registries were invited to participate as the linkage study progressed. Participation in this linkage study is voluntary and no reimbursement is provided. Participation in the linkage study is voluntary and no reimbursement is provided. Participation in the linkage study is voluntary and no reimbursement is provided.

Results: In 2010, 81 state cancer registries responded to this participation. In the first annual linkage in 2010, 61 registries agreed to participate. In the second annual data linkage in 2011, 55 registries agreed to participate. In the third annual data linkage in 2012, 50 registries agreed to participate.

Conclusions: The participating registries are in all 50 states and the District of Columbia. This linkage study is voluntary and no reimbursement is provided. Participation in the linkage study is voluntary and no reimbursement is provided. Participation in the linkage study is voluntary and no reimbursement is provided.

ABMS
- The aim of this protocol is to describe the variation of state cancer registry approval required for participation in this linkage study and to provide a summary of the first three annual data linkages.

METHODS
Registration Recruitment
- The FPR is available to all RTI-HS approved the study in 2010, and approval is renewed annually.
- In May 2010, RTI Health Solutions (RTI-HS) invited cancer registries in all 50 states and the District of Columbia in this first linkage.

RESULTS
The average time for the 39 participating states to become linkage ready was 149 days (range, 44–477 days).

CONCLUSIONS
After three annual linkages, no matches have been found between patients enrolled in the registries participating in this linkage study and those enrolled in the FPR. The Forteo Patient Registry study procedures, data collection, analysis, and dissemination of the linkage findings are feasible for a large number of states to implement. Further, the linkage results provide evidence that osteosarcoma is a rare event. Further research is needed to determine the incidence of osteosarcoma.

REFERENCES
1. Sato M. Bone neoplasms in F344 rats given...