Collaboration With Multiple State Cancer Registries for a Data Linkage Drug Safety Surveillance Study – Yes You Can!

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ABSTRACT

Background: The Forteo Patient Registry is a solicitation-prospectus enrolled cohort study designed to assess the incidence and risk of osteoporotic fractures (OF) in postmenopausal women with osteoporosis (OP). To date, 407 578 postmenopausal women have been enrolled in the Forteo Patient Registry. The Forteo Patient Registry is a data linkage study involving many state cancer registries with the purpose of expanding the understanding of the safety of medications.

Methods: Cancer registries in all 50 states and the District of Columbia were invited to participate in the 2010 Data Linkage Study which was conducted to link the Forteo Patient Registry with state cancer registries. Registry data indicate that it is feasible for a large number of registries to perform a data linkage study and the variation among registries is low and therefore data linkage is feasible across many states with minimal customization.

RESULTS

• 42 of 42 registries (91–120 days, 31–60 days, <14 days) completed the initial linkage approval process.

• 36 of the 42 registries (86%) approved the RTI IRB review. At least one additional approval was required at 27 (covering 70% of the adult US population) registries.

• The study has been approved by the RTI Institutional Review Board of North Carolina (IRB). The progress with participating state cancer registries is shown in Figure 1.

• The Forteo Patient Registry database and cases of osteosarcoma diagnosed since January 1, 2009, from the 42 registries are expected to be published in the future.

• Figure 3 describes the results of the initial effort to identify and enroll participating registries.

• Participation involves providing signed contact information for review and approval requirements that may vary by state. A standardized research application and approval process is being developed to accommodate the variety of review and approval requirements that may exist among states.

CONCLUSIONS

• The results of the first linkage with the Forteo Patient Registry indicate that it is feasible for a large number of registries to perform a data linkage study.

• Cancer registries offer a primary source of patient-level identifying data in the US, many new therapies will require participation of multiple registries.

• Due to the 9- to 18-month lag time between the date of cancer diagnosis and date the data are available, the opportunity for further collaboration is high, particularly for public and private registries in the long-term care or cancer-associated care.

• In the absence of a national cancer registry with patient-level identifying data in the US, many studies will require participation of multiple state cancer registries.

REFERENCES

1. Vahle JL, Long GG, Sandusky G, Westmore M, Ma YL, Sato M. Bone neoplasms in F344 rats given teriparatide [rhPTH(1-34)] are

DISCLOSURE

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