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Prescribing decisions should be made based on the approved package insert in the country of prescription

Sponsor/company:	Bristol-Myers Squibb and Sanofi-Aventis	**ClinicalTrials.gov Identifier:**	NCT00258921
		Study Code:	R_9511
Generic drug name:	Irbesartan	**Date:**	30 Oct 2007

Title of the study:	Reasons for not Intensifying Antihypertensive Treatment (RIAT) An international registry in essential hypertension
Investigator(s):	Pr P FERRARI, Clinical Director, Department of Nephrology, Fremantle Hospital, Fremantle WA6160, AUSTRALIA
Study center(s):	1596 centers Argentina (13); China (92); Colombia (57); Dominican Republic (4); Indonesia (114), Korea (808); Lebanon (103); Malaysia (117); Mexico (76); Morocco (41); Philippines (9); Russia (53); Saudi Arabia (10); Singapore (18); Taiwan (56); Vietnam (25)
Study period: Date first subject enrolled: 01-Jan-2004 Date last subject completed: 25-Jul-2006	**Phase of development:** Prospective registry
Objectives:	The objective of this program was to support physicians in their active management of hypertensive patients. RIAT aimed at providing responses to 5 key objectives. **Primary objectives** 1. What is the BP targeted by physicians according to existing associated risk factors? 2. What are the reasons for not modifying / adapting an antihypertensive treatment while individual BP targeted figures have not been reached? **Secondary objectives** 1. What class (es) of antihypertensive drug is (are) prescribed according to the presence of risk factors or compelling indications (diabetes, chronic kidney disease, heart failure, post-MI, etc.)? 2. What are the reasons leading to modify the treatment while BP targeted figures have been reached? 3. Which percentage of patients really reached the predefined target figures?

Methodology:	**RIAT** was a program proposed in 3 (optional) steps: -The first step identified the reference guidelines and recommendations in each country for the management of (and therapeutic targets for) hypertensive patients. -The second step was a survey of the variance between individual targets defined by general practitioners (GPs) in their practice and national and international guidelines/recommendations. -The third step was a prospective registry where the physicians collected patient data at baseline and then determine individual BP values as targets to be reached at subsequent visits.
Number of subjects:	Planned: 23570
Evaluated:	35302 subjects recruited and analyzed
Diagnosis and criteria for inclusion:	**Inclusion criteria** Adult hypertensive patients of either gender with essential hypertension: - either newly diagnosed and untreated - or previously treated and uncontrolled **Exclusion criteria** Known secondary hypertension
Investigational product:	The physician was entirely free to choose the antihypertensive drug regimen at each visit. Irbesartan and Irbesartan hydrochlorothiazide were proposed as one option for antihypertensive treatment.
Duration of treatment: NA	**Duration of observation:** The duration of the follow-up per patient was recommended to be at least 3 months in order to assess the adherence (duration of treatment). The study duration was decided by each country. In average, 3 follow-up visits (V2, V3 and V4) were performed for most of the subjects (4 follow-up visits were performed in China). The time interval between each visit was in average ~ 1 month
Criteria for evaluation:	
Efficacy:	Target BP • BP target for the individual patient suggested by the national/ international guidelines. • BP target that the practitioner considered for his/her patient Current Blood pressure (SBP/DBP) at each visit Demographic information : Age, Gender, Height, Weight Major risk factors :Body mass index (BMI) equal to or over 30 Kg/m², smoking habits, diabetes (type 1 or type 2), physical inactivity, dyslipidemia, family history of premature cardiovascular disease Target-organ damage: Micro- or macroalbuminuria, increased serum creatinin levels, left ventricular hypertrophy Associated (or prior) clinical conditions: Cerebrovascular conditions (stroke, TIA), coronary heart disease (MI, angina pectoris, coronary revascularization), congestive heart failure, peripheral arterial disease (PAD), retinopathy (hemorrhage, papillary edema) Treatment(s) prescribed: Class, trade name

Safety:	As this registry was not a clinical trial, no adverse event (AE) form was provided with the DCF. If an adverse drug reaction (or lack of efficacy) occured during the registry, the physician had to report it to the Marketing Authorization holder of the suspected drug as it is the case for any spontaneous report with marketed products. In case of adverse drug reaction (ADR) with irbesartan or irbesartan/hydrochlorothiazide, the physician had to inform Sanofi-aventis representatives .
Statistical methods:	Statistical analysis was based on all patients enrolled in the registry. Data were summarized using mean, median, standard deviation and range for continuous parameters and counts and percentages for categorical parameters. All statistical tests were performed using two-tailed tests at a 5% level of significance. Descriptive analyses were performed. Patient's characteristics (demographic data, risk profile, treatment) were described. Subgroup analyses were performed in some secondary populations.
Summary:	35,302 patients (17,722 men (50.2%) and 17,565 women (49.8%) were included in the survey by 1596 centers. The mean age was 59.2 ± 12.1 years. Hypertension was newly diagnosed for 11,138 patients (31.7%). Of the usual risk factors for hypertension, the most frequently observed was physical inactivity. 9,954 patients were known to have diabetes (28.2%). On inclusion, 7027 patients (20.8%) had grade III hypertension, 15,207 patients (45.1%) had grade II hypertension and 11,519 patients (34.1%) had grade I hypertension. At baseline, SBP averaged 158.7 ± 15.3 mmHg and DBP averaged 95.2 ± 12.0 mmHg.
Efficacy results	**The mean BP target values** set by the physicians as a function of the various risk factors ranged from 133.2 to 136.9 mmHg for SBP and from 83.9 to 87.3 mmHg for DBP. For patients with type II diabetes mellitus, the target values set by physicians at baseline were significantly lower: SBP = 131.9 ± 5.4 and DBP = 82.3 ± 4.6 mmHg. **According to the number of risk factors**, individual target SBP and DBP values differed significantly: with no factors, the target SBP was 138.2 ± 4.9 mmHg and the target DBP was 88.4 ± 3.7 mmHg; for 1 or 2 factors the target SBP was 135.7 ± 6.2 mmHg and target DBP was 86.1 ± 5.1 mmHg; for 3 or more factors; the target SBP was 133.6 ± 6.8 mmHg and the target DBP was 84.4 ± 5.4 mmHg. **Reasons for not modifying the treatment**: at V2, the investigator estimated that the target BP had not been reached in 21,162 patients (63.4%) and chose not to modify the treatment in 16,904 of these individuals (79.9%). The most commonly cited reason was the time factor (in 85.3% of cases). At V3, the investigator estimated that the target had not been reached in 15,880 patients (47.4%) and chose not to modify the treatment in 13,034 of these individuals (82.1%). The most commonly cited reason was the time factor (in 76.4% of cases). At V4, the target BP had not been reached by 5,152 patients (16.0%) and the investigator chose not to modify the treatment in 3,240 of these individuals (62.9%). The most commonly cited reason was again the time factor (in 34.7% of cases). **The percentage of patients who had achieved the target increased over the course of the program**: according to the BP values measured, the percentage of patients having achieved the target was 34.6% at V2, 50.0% at V3 and 80.7% at V4.

Efficacy results:	**The number of different antihypertensive treatments prescribed before reaching the target value** for the first time was : one single drug for 19,199 patients (62.5%), two drugs for 6,574 patients (21.4%), three drugs for 3300 patients (10.8%) and four or more for 1,392 patients (4.6%). **Among the patients who reached the BP targets, a treatment modification was observed** in 5.2% of patients at V2, 4.2% at V3 and 2.1% at V4. The most frequent reason for modifying the treatment was a side effect (nearly 30% of the cases).
Safety results:	NA
Date of report:	14-May-2007