

The following title (11) discloses the inclusion criterion that the patients must never have received chemotherapy (they must be chemotherapy-naïve). Another inclusion criterion is that the patients must have progressive metastatic prostate cancer. Yet another inclusion criterion is a requirement for failure, that is, that they must have already been treated for this cancer with androgen deprivation, and that this therapy failed.

- *Title: A Multinational Phase 3, Randomized, Double-Blind, Placebo-Controlled Efficacy and Safety Study of Oral MDV3100 in Chemotherapy-Naïve Patients with Progressive Metastatic Prostate Cancer Who Have Failed Androgen Deprivation Therapy (12)*

The following title reveals that study subjects entering the trial must have received anti-EGFR antibody (13).

- *Title: An Open Label, Partially Randomised Phase II Study to Investigate the Efficacy and Safety of BIBW 2992 in Patients with Metastatic Colorectal Cancer Who Never Received Prior Anti-EGFR (Epidermal Growth Factor Receptor) Treatment (14)*

According to the next title (15), one of the inclusion criteria is that the virus infecting the

study subjects be one of five different genotypes. As a general proposition, subtypes of a disease, such as genotype of a virus, or stage of a disease, can be part of the title.

- *Title: An Open-Label Trial in Genotype 2, 3, 4, 5 and 6 Hepatitis C-infected Subjects to Evaluate the Antiviral Activity, Safety, Tolerability and Pharmacokinetics of TMC435350 Following 7 Days Once Daily Dosing as Monotherapy (16)*

Published reports of clinical trials also describe the inclusion and exclusion criteria. Roh et al. (17) provide one of the most comprehensive sets of inclusion and exclusion criteria ever published in a medical journal.

b. Stratification of Study Subjects

Subjects enrolled in clinical trials are typically classified into various strata, in a process called stratification. Stratification occurs at about the same time as randomization, and it occurs before subjects receive the experimental or control treatments. Stratification refers to a scheme where subgroups of a study population are classified according to stage of disease, gender, age, location of the clinic, prior therapy (if any), cytogenetics, or biomarker

¹¹Beer TM, Armstrong AJ, Rathkopf DE, et al. Enzalutamide in metastatic prostate cancer before chemotherapy. *N. Engl. J. Med.* 2014;371:424–33.

¹²Beer TM, Armstrong AJ, Rathkopf DE, et al. Enzalutamide in metastatic prostate cancer before chemotherapy. *N. Engl. J. Med.* 2014;371:424–33.

¹³Boehringer Ingelheim Pharmaceuticals. <http://www.clinicaltrials.gov/ct2/show/NCT01152437?term=%22never+received%22&rank=14>.

¹⁴Boehringer Ingelheim Pharmaceuticals. <http://www.clinicaltrials.gov/ct2/show/NCT01152437?term=%22never+received%22&rank=14>.

¹⁵Tibotec Pharmaceuticals. <http://www.clinicaltrials.gov/ct2/show/NCT00812331?cond=hepatitis+c&rank=1> [accessed from www.clinicaltrials.gov on 27.09.10].

¹⁶Tibotec Pharmaceuticals. <http://www.clinicaltrials.gov/ct2/show/NCT00812331?cond=hepatitis+c&rank=1> [accessed from www.clinicaltrials.gov on 27.09.10].

¹⁷Roh MS, Colangelo LH, O'Connell MJ, et al. Preoperative multimodality therapy improves disease-free survival in patients with carcinoma of the rectum: NSABP R-03. *J. Clin. Oncol.* 2009;27:5124–30.