



EUGenMed

Roadmap for Including Sex & Gender in Biomedical & Public Health Research

Hildrun Sundseth

President

European Institute of Women's Health





EUGenMed Partners



- **Coordinator:** Charité-University Medicine Berlin
Institute for Gender in Medicine (GIM)
 - European Institute of Women's Health
 - Maastricht University
-
- 2 year project, starting Oct 2013



www.eugenmed.eu



EUGenMed Project

- The project will develop a Roadmap for implementing sex and gender aspects into biomedical and health research
- It will build on existing activities to develop an interdisciplinary, inclusive European Gender Health Network.
- Major activities:
 - Kick-off conference; workshops; roadmap conference
 - Generating material for different target audiences
 - Identification of future priorities and recommendations

EUGenMed

Roadmap Workshops

- WS 1: Sex and Gender in clinical research and clinical pharmacology (Charité)
- WS 2: Sex and Gender in public health and prevention, focus on risk factors for non-communicable diseases (Maastricht University)
- WS 3: Sex differences in basic biomedical research (Charité)
- **WS 4: Sex and Gender in medicines regulation** Sex and Gender in medical education (EIWH)

Sex & Gender: IoM Definition

- **Sex:** Used as a classification, generally as male or female, according to the reproductive organs and functions that derive from chromosomal complement
XY vs. XX
- **Gender:** Used to refer to a person's self-representation as male or female, or how that person is responded to by social institutions on the basis of the individual's gender presentation
Masculine vs. feminine

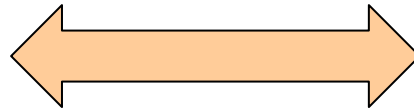
The Interaction Between Sex and Gender

Biological Dimension

- The biological/ sex differences between females and males are relevant for the diagnosis, treatment and progression of various diseases and medical conditions.

Social Dimension

- Important social consequences which affect health include education, employment and family life.
- Socio-economic, educational cultural, ethnicity differences can impact on patterns of behaviour and access to resources.



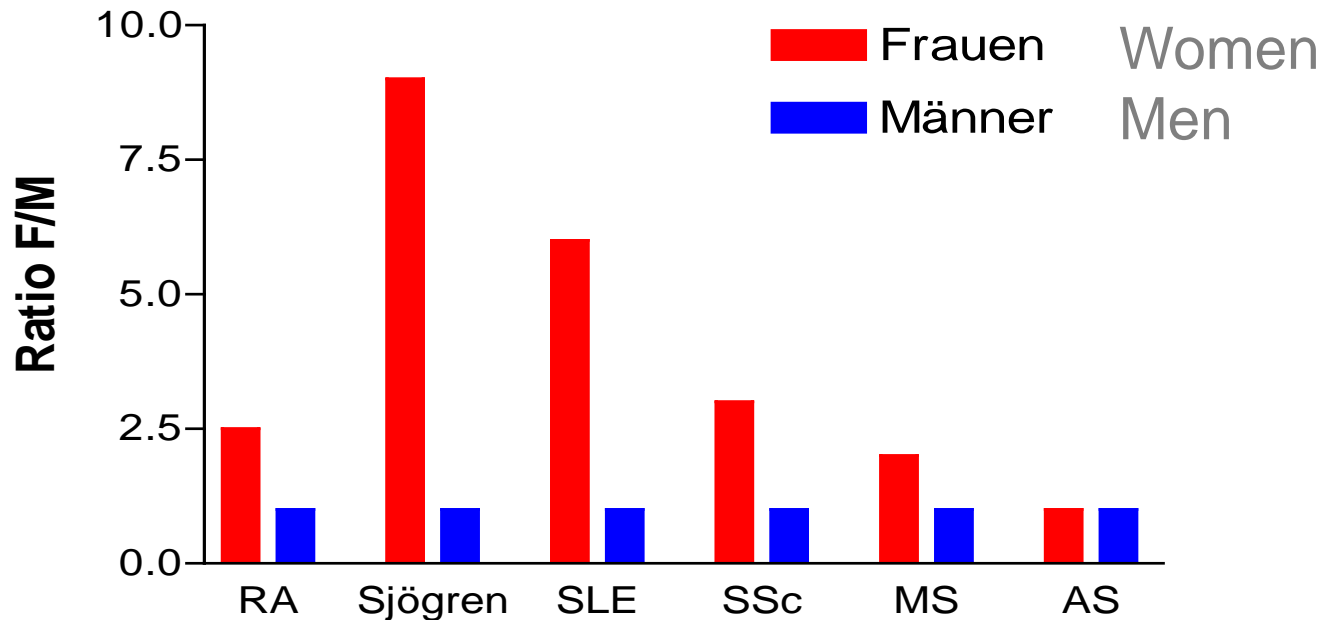
Often Sex and Gender interact - epigenetics

Facts

- Women live longer than men
- The incidence and prevalence of diseases differ between men and women
- Women have higher rates of osteoporosis, autoimmune diseases, eating disorder, Alzheimers, etc
- Men have higher rates of Parkinsons, chronic liver disease, violence-related injuries, lung cancer, etc
- Some diseases affect men and women differently: CVD, lung cancer, diabetes, depression, etc

Autoimmune Disease: Women and Men

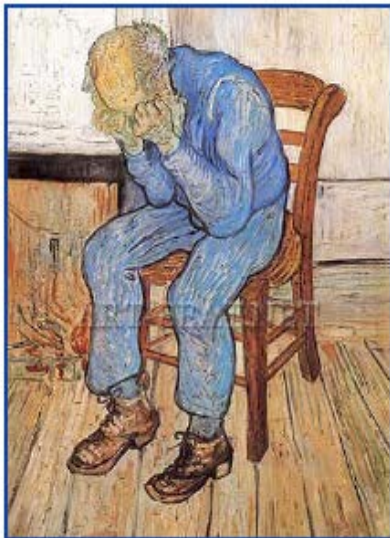
- Higher prevalence in women
- Research frequently neglects sex & gender differences



RA: rheumatoid arthritis, SLE: lupus erythematoses, SSc: Scleroderma; MS: multiple sclerosis, AS: spondylitis ankylosans

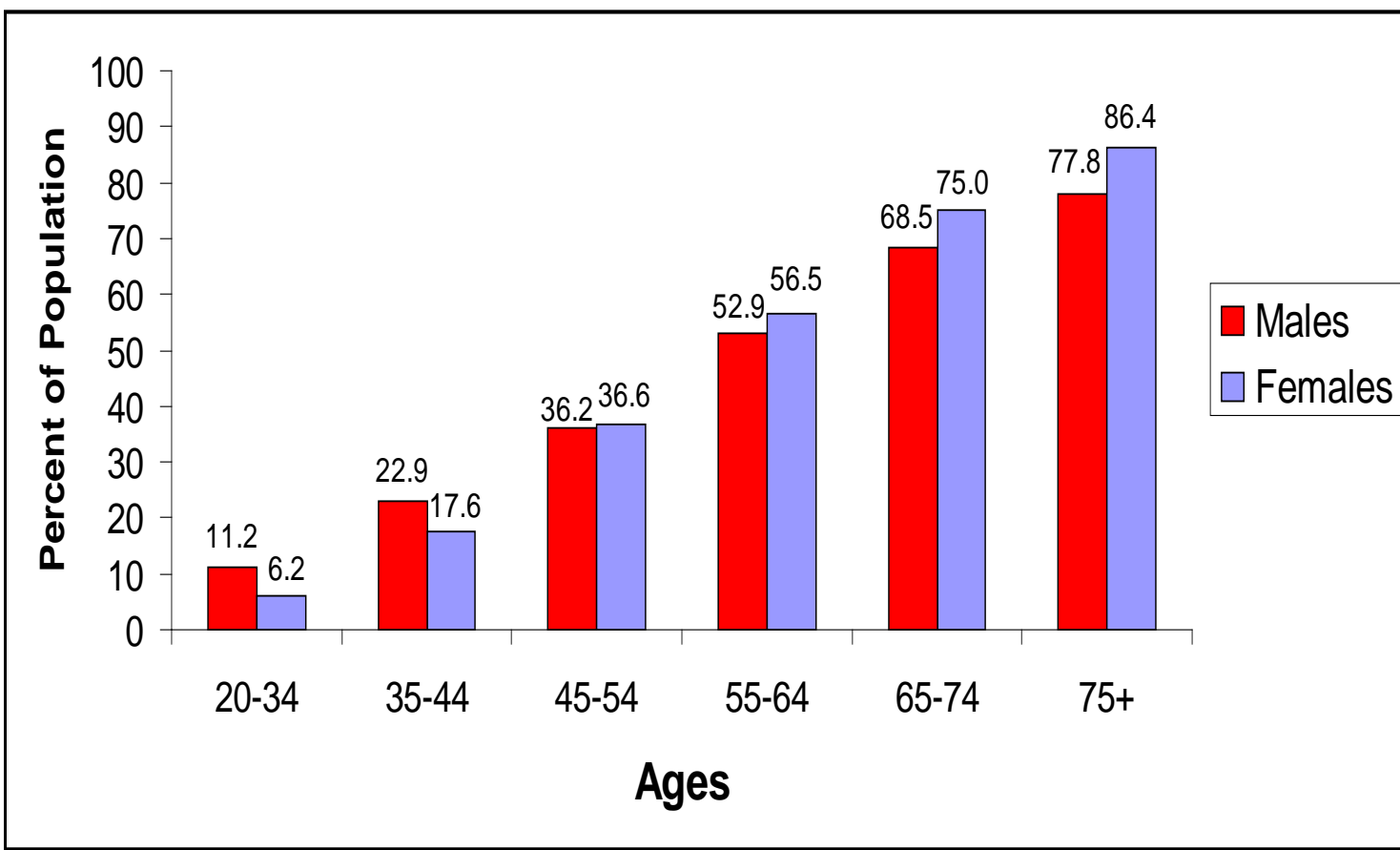
Mental Illness: Men & Women

- Men:
 - Antisocial personality
 - Substance abuse
 - Completed suicide



- Women:
 - Anxiety, depression
 - Eating disorders
 - Attempted suicide

Prevalence of CVD by Gender and Age



CDC/NCHS and NHLBI 2008

Medicines Regulation

Why consider S&G

- Both Sex and Gender matter in health
- Including Sex and Gender in biomedical research is good science and an important quality and safety issue
- In a just society, biomedical research must provide optimal treatment for both men and women

Medicines Regulation

Why consider S&G

- Medicines are safer and more effective for all when clinical research includes diverse population groups of all ages
- Women are under-represented in many clinical trials and if included, robust analysis is often lacking
- Sex differences of tissues and cells, every cell has a sex
- Women metabolise medicines differently
example: Ambien - FDA halved dose for women



Sex and Gender in Medicines Regulation



European Heart Journal (2010) **31**, 1677–1685
doi:10.1093/eurheartj/ehq094

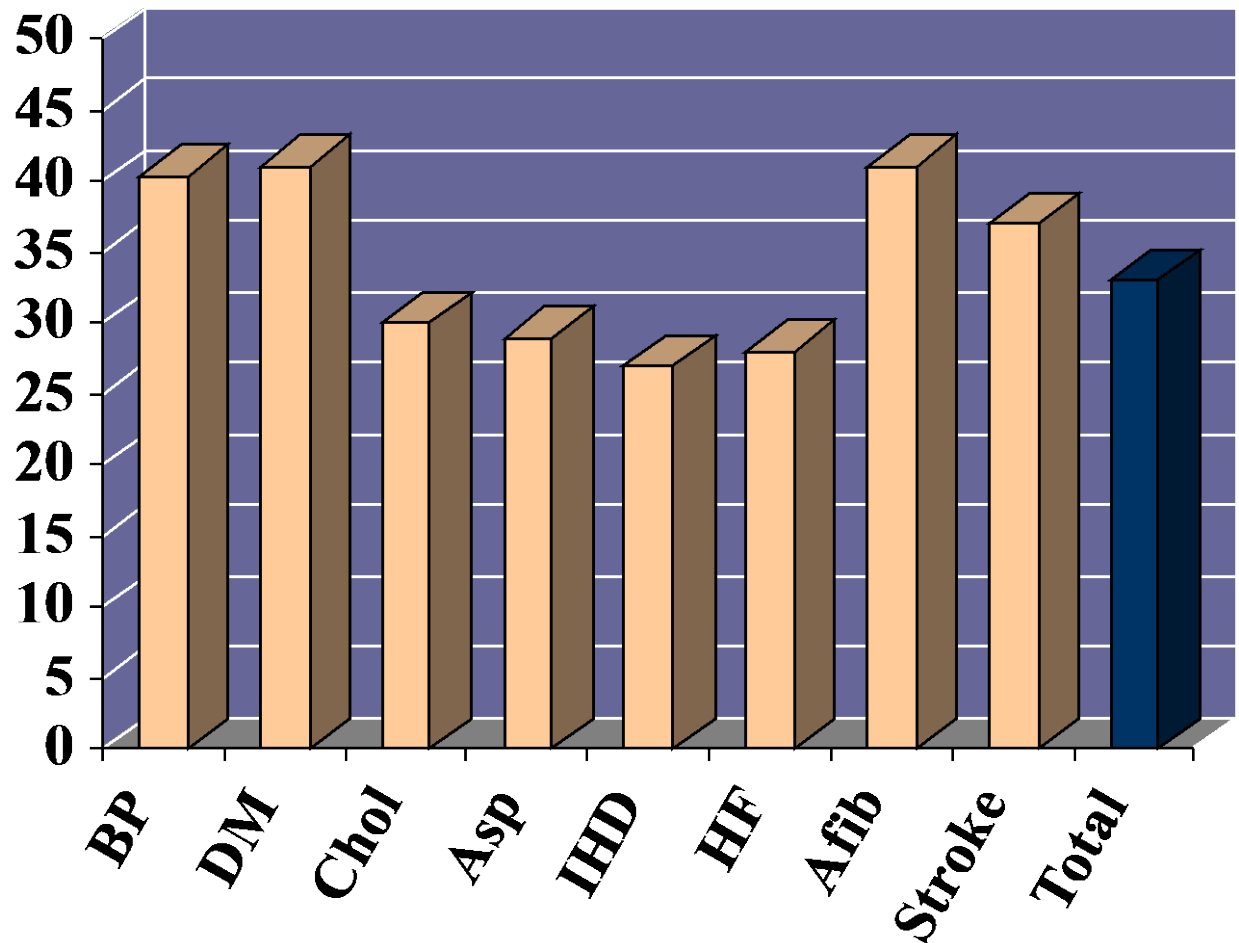
CURRENT OPINION

Women and research on cardiovascular diseases in Europe: a report from the European Heart Health Strategy (EuroHeart) project

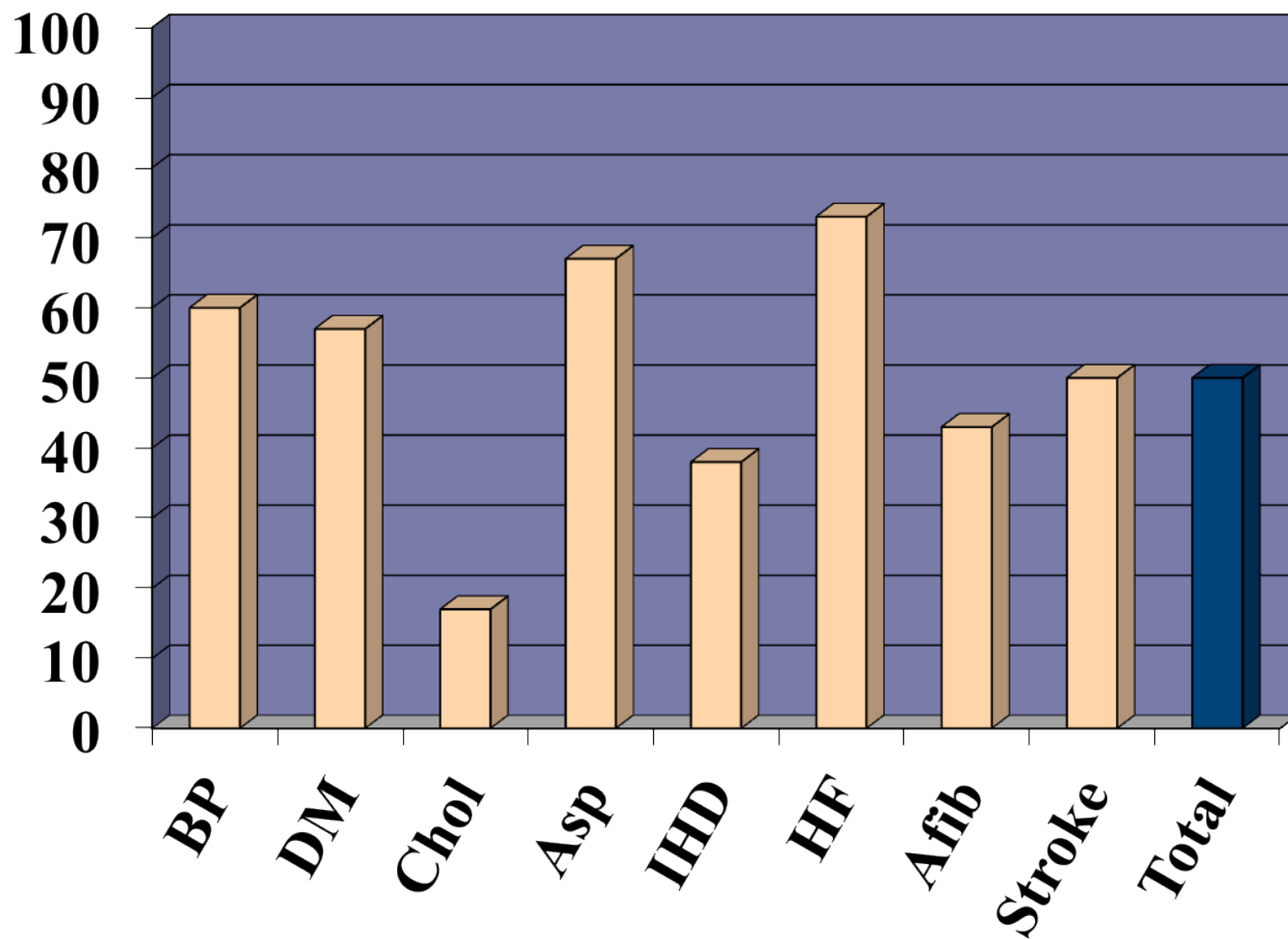
Marco Stramba-Badiale*

Department of Rehabilitation Medicine, IRCCS Istituto Auxologico Italiano, Via Mosè Bianchi, 90, 20149 Milan, Italy

Percentage (%) of Women in CVD Clinical Trials



CVD – Clinical Trials with Analysis by Gender %



Sex and Gender in Medicines Regulation

- Translating the evidence from S&G research into regulatory practice will lead to more targeted, effective opportunities for prevention, diagnosis, treatment and care.

WS Medicines Regulation Recommendations

- Ethics Committees to develop guidelines that address inclusion of women in CTs, following good practice example from Medical University of Vienna
- Stakeholders to propose IMI project to develop robust methodology for subgroup analysis, address existing barriers for the recruitment and retention of women and older people in CTs

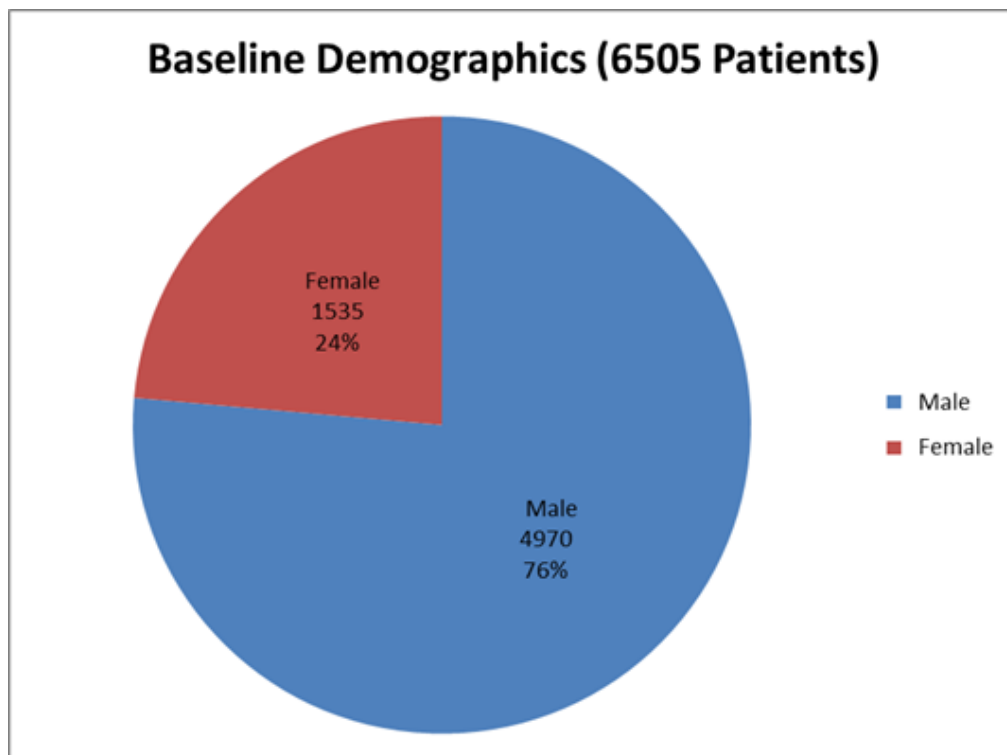
WS Medicines Regulation Recommendations

- In preparation of implementing new Clinical Trials Regulation, EMA together with key stakeholders draft Guidelines on S&G analysis in CTs (example: Health Canada)
- Improve rigorous sex and age-specific pharmacovigilance reporting for existing products
- Address knowledge gap: develop regulatory framework for safe use of medicines during pregnancy: post-marketing data collection, common rules for pregnancy exposure registries, etc.

WS Medicines Regulation Recommendations

- EMA to make sex- and age-specific data more readily available and transparent

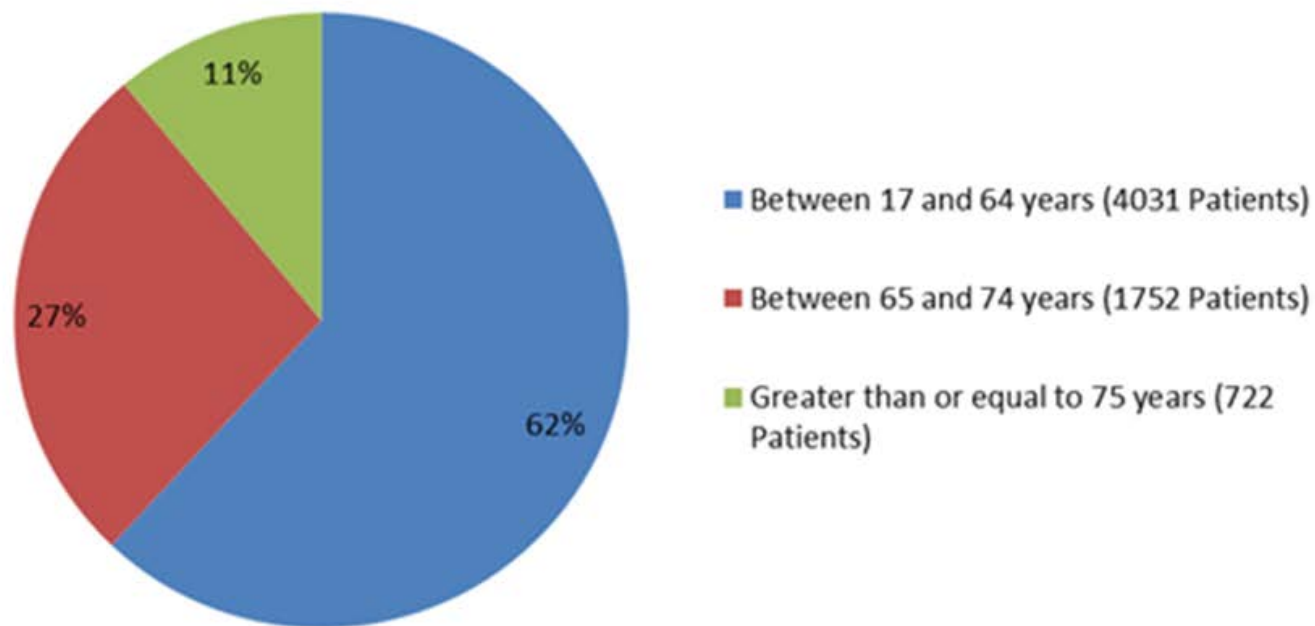
Example: FDA Snapshot on heart failure drug: *Corlanor*



Source: FDA, 2015

Example: FDA Snapshot Heart Failure drug: *Corlanor*

Baseline Demographics (6505 Patients)



Source: FDA, 2015

Thank you. Any questions?

European Institute of Women's Health

33 Pearse Street, Dublin 2, Ireland

<http://eurohealth.ie>

+353-1-671-5691 (phone)



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