CLINICAL TRIALS IN LOW AND MIDDLE INCOME COUNTRIES: APPROACH TO CONTINUED ACCESS TO INVESTIGATIONAL MEDICINES

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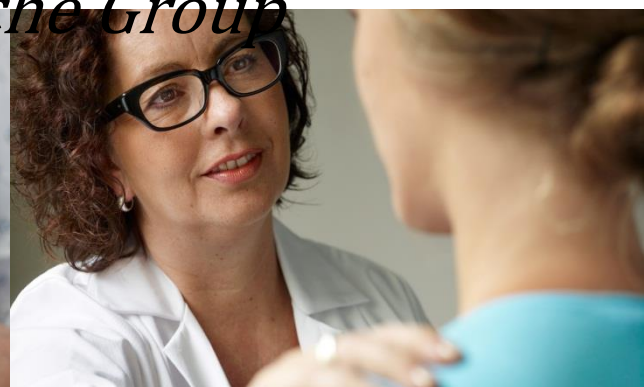
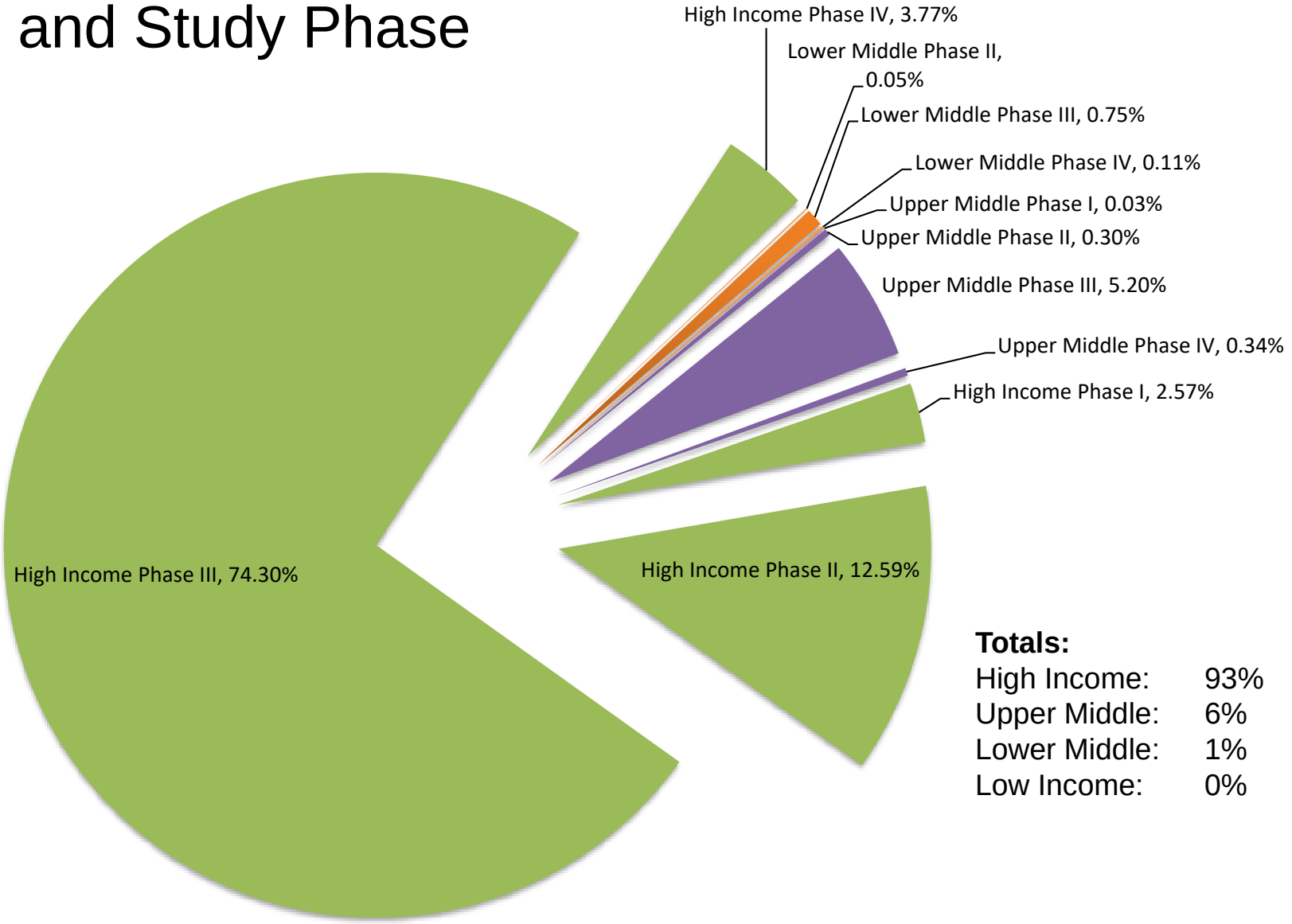


Clinical Trial Participants by Country Income Level and Study Phase



Totals:

High Income:	93%
Upper Middle:	6%
Lower Middle:	1%
Low Income:	0%

Source: Roche Clinical Trial Management System; all patients enrolled in trials with "active" status as of April 2017

Example Case Study: Continued Access for Etrolizumab in Ulcerative Colitis Clinical Trials

- Following phase III trials (16 months long), participants may continue to receive etrolizumab for up to 7 years or until commercial availability; longer for patients with ongoing need after commercial availability (per Roche Continued Access Policy)
- These trials will enroll up to 2600 participants in 44 countries (income level per World Bank definitions, 2017):
  - High Income: 68%
  - Upper Middle Income: 25%
  - Lower Middle Income: 7%

Source: https://clinicaltrials.gov. Study identifiers: NCT02118584, NCT01461317, NCT02163759, NCT02171429, NCT02100696, NCT02165215 and NCT02136069

ROCHE CONTINUED ACCESS POLICY

- Roche offers patients who participate in Roche-sponsored clinical trials continued access to the investigational medicinal product (IMP) after completion of the trial, free of charge, if:
  - Patient has a life threatening or severe medical condition that requires continued administration of IMP
  - No appropriate alternative treatments available to the patient
  - Patient and doctor comply with legal/regulatory requirements

- Roche will not provide continued access to IMP if:
  - IMP is commercially marketed in the patient's country and is reasonably accessible to the patient (e.g., is covered by the patient's insurance or wouldn't otherwise create a financial hardship)
  - Roche has discontinued development of the IMP
  - Data suggest reasonable safety/efficacy concerns with IMP
  - Provision of IMP not permitted under laws and regulations of the patient's country

Source: Roche Global Policy on Continued Access to Investigational Medicinal Product, 18 Sep 2013
www.roche.com

ROCHE POSITION ON CLINICAL TRIALS IN LOW AND MIDDLE INCOME COUNTRIES

- The same international regulations and high standards of ethical conduct and scientific integrity will be adhered to in all countries
- Roche intends to seek marketing authorization in all countries where we conduct clinical studies for a particular medicine

Source: Roche Position on Clinical Research, 2008, update 2017. www.roche.com

Post-Trial Responsibilities Working Group

Multi-Stakeholder Collaboration

Launched in 2015

To Deliver:

MULTI-REGIONAL CLINICAL TRIALS

THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

1. Common terminology
2. Case studies/scenarios portfolio
3. Ethics and practical framework for PTR:
   - **Guidance Document** – responsibilities of stakeholders, based on basic ethical principles
   - **Toolkit** - practical tool to assess PTR
   - **Principles Document** – summarizing major concepts on PTR

http://mrctcenter.org/projects/post-trial-responsibilities/

Post-Trial Responsibilities Working Group