From molecule to medicine: MMV's R&D process

1. Find hits (those compounds able to kill the parasite)
2. Test hits in vitro and in vivo in the laboratory, for drug-like qualities to produce a lead compound
3. Improve lead compound's properties by re-engineering or optimizing it to remove any undesirable features until it can be considered a drug candidate
4. Test the safety of the drug candidate in the lab
5. Phase I clinical trials to determine the safety and appropriate dose of the drug in humans – healthy volunteers without the disease (~100 people)
6. Phase II clinical trials to ascertain safety, and ability of the drug to cure malaria – also known as 'proof-of-concept' (~100 – 600 patients)
7. Phase III clinical trials to compare the safety and efficacy of the drug, head-to-head, against the best currently available treatment (~3000 patients)
8. Registration by a stringent drug regulatory authority and/or WHO prequalification that thoroughly evaluates all aspects of the medicine in order to decide if it should be deemed a legitimate pharmaceutical product

*ICH: The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

For further information see www.mmv.org