It is with great pride that I participate in this ceremony of the University of Malta, a University which traces its origins to the Collegium Melitense which was set up through a direct papal intervention in 1592. This University has made milestone achievements since inception. Evidence of this is the fact that as I speak today, there are over 11,000 students, including 800 international students studying at this institution. In my opinion, such achievements have only been possible because of the adaptive nature of this University, which is intrinsically bound with its innate spirit of offering outstanding education to all those who yearn for knowledge. Nowadays, this is more aptly seen through the various collaborations and partnerships which are being spearheaded with foreign universities. Indeed, change does not necessarily mean improvement, but there can be no improvement without change.

With these reflections in mind, hand on heart, I must admit that when I read, and read again, the words which John Masefield, English poet, penned in 1946 for the inauguration of the Chancellor of the University of Sheffield, I like to dream that he had our University in mind ...

"... There are few earthly things more beautiful than a university.  
It is a place where those who hate ignorance may strive to know,  
where those who perceive truth may strive to make others see;  
where seekers and learners alike,  
banded together in the search for knowledge ..."

I ask you, is this fraternal movement of bridging knowledge not the very soul of our great University?

During the next few minutes, I wish that you accompany me along the memory lane whilst I share two stories. I promise that I will be brief.

The first story is how I followed my dream.

Why did I choose to read a PhD? I considered it a means to better oneself and to advance career-wise; at the same time, I was always fascinated by the literal meaning of the acronym ‘PhD’, i.e. ‘teacher of philosophy’ from the Latin ‘Philosophiae Doctor’. But then, what is philosophy? The Cambridge dictionary defines it as ‘the use of reason in understanding such things as the nature of the real world and existence, the use and limits of knowledge, and the principles of moral judgment’. So, to me, it seemed that the attainment of a PhD went beyond the successful accomplishment of studies in a particular area. Truth be told, the very process of reading for a PhD moulds one’s mind and spirit to achieve self-discipline and better judgement ... and indeed, believe you me, reading for a PhD is life-changing. Not the actual ceremony, obviously. What leads to the ceremony is what changes a person …

At this stage, a second question naturally crops up. Why did I choose to read a PhD with the Paediatrics Department? It all began many years back when I was surfing the internet to garner ideas for the editorial of The Synapse Medical Magazine, of which I am the editor. I remember that I encountered a most interesting story which I would like to share with you. In a distant time - it was
1850 – and in a distant land - US - Mrs Winslow’s Soothing Syrup started to be marketed to treat teething and loose motions in children. In case someone questions what the news about such a remedy is, I need to add that the active ingredients were alcohol and ... opium! The Hampshire Telegraph and Sussex Chronicle of the 9th January 1875 advertised this cure as ... “Advice to mothers: Are you broken in your rest by a sick child suffering with the pain of cutting teeth? Go at once to a chemist and get a bottle of Mrs Winslow’s Soothing Syrup .... It soothes the child, it softens the gums, allays all pain, relieves wind, regulates the bowels, and is the best known remedy for dysentery and diarrhea, whether arising from teething or other causes.”

Obviously, there was a growing body of evidence on the harmful effects of the active ingredients which were being administered to children at that time, including heroin, chloroform and even cocaine. In fact, deaths were reported following the use of Mrs Winslow’s Soothing Syrup. However, although these reports started in 1888, remarkably, the product only started to be withdrawn from the markets in 1906 ... almost 20 years later.

Although such anecdotes seem distant to us, there were other reported fatalities, nearer to us, arising from paediatric medicinal uses. The sulphanilamide elixir disaster occurred in 1937, shortly after its introduction, when diethylene glycol was used as a diluent in the formulation of the elixir. It caused the death of 105 patients, including 34 children, because of the nephrotoxic effects of diethylene glycol. Despite all this, barely 20 years later, another therapeutic disaster occurred, the thalidomide-induced phocomelia, which affected thousands of infants. The reasoning behind this practice is that these ‘therapeutic orphans’ have always been purported to be ‘small adults’. This is obviously not the case. Children are characterised by continuous ontogenesis and it is not practical to titrate the dosing using the proportionality rule.

Such unfortunate historical episodes have served to shape the three modern pillars of the regulatory infrastructure which govern medicinal products today. These are quality, safety and efficacy. Before I progress any further, it is wise to appreciate the exact meaning of these three words which are often taken for granted. Quality is the demonstration that the finished medicinal product being administered to patients is consistently produced in accordance with validated specifications and that the product is stable until its expiry date. On the other hand, safety entails that a risk-benefit analysis has been established and the product is safe to be used in a duly informed population, at the recommended dose. Efficacy means that the claims for the effectiveness of a product to be used for the prevention and/or treatment of a medical condition have been substantiated by clinical testing.

Despite this historical background, studies conducted in various countries indicate that the incidence of off-label (OL) or unlicensed (UL) medicines in children can be as high as 100% in specific settings. At face value this seems to indicate that, today, medicines which are not duly licensed for children are still being used in this vulnerable population. This is where our research was conceived; we investigated the local OL and UL paediatric prescribing of medicines, in line with the Paediatric Regulation (Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for Paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004). One of our investigations found that locally, almost one in two medicines prescribed to children in the community setting are OL or UL. We found that there are numerous contributing factors for this high incidence, including lack of appropriately licensed medicines and failure by prescribers to follow the recommendations detailed in the product literature. One must clarify that the main reason for the latter finding is that identical medicinal products produced by different pharmaceutical companies may differ in their paediatric information. These regulatory shortcomings are further accentuated by the fact that presently, there is a lack of harmonisation between published literature, e.g. BNF, and the product literature of specific medicines. In fact, when medicines are used in an OL or UL manner, this does not necessarily mean that information on the safety and efficacy of these medicines is not available. Indeed, it has been advocated that failure to use medicines in an OL or UL manner in specific scenarios, under the appropriate standard of care, can actually translate into malpractice, since this would constitute the most rational clinical decision to take, when one considers the risk-benefit analysis and lack of suitable alternatives. Locally we are fortunate enough to have the aforementioned shortcomings aptly compensated by prescribers’ expertise in treatment practices. Nonetheless, research is of the utmost importance to further increase the repository of evidence-based information and optimise therapeutic practices.

This brings us to the second story, where I will briefly discuss how this dream moulded my perception of life.

At the beginning I confessed that the very process of reading for a PhD shapes one’s mind and soul to achieve self-discipline and better judgement. This comes at a cost. There are moments when you think that reading for a PhD is like hitting your thumb with a hammer. It feels really good when you stop! These constitute the bad moments ... when everything seems to collapse. Unfortunately, one seems to see things worse than they actually are when you ask for funding and you are told that there is none available. However, on a positive note, despite this and various other shortcomings, I still managed to successfully finish my PhD. If I did it, so can you.
At this stage, I need to thank all those who were my champions during this long process. I was fortunate enough to be entrusted with their vision and emotional intelligence. I need to thank my tutor Professor Victor Grech, as well as Professor Richard Muscat, Professor Simon Attard Montalto, Professor Alex Felice, Dr Paul Vassallo-Agius and Dr Herbert Lenicker for their invaluable advice. I was fortunate enough to be entrusted with their gifts of knowledge and patience. I am also indebted towards Professor Liberato Camilleri who shared his expertise, in a most dedicated manner, for the statistical analysis. I was fortunate enough to be entrusted with his gift of kindness. Special thanks go to my sweet wife Mellyora, my mother Catherine, my father William, my sister Rita, my uncle Nazzareno and my late aunty Maria. I was fortunate enough to be entrusted with their gifts of faithfulness and love. Last but not least I must thank God Almighty. I was fortunate enough to be entrusted with His gifts of peace and self-control. I still remember the many times I sought refuge in Psalm 23,

“In green pastures he makes me lie down;
   to still waters he leads me;
   he restores my soul.
   He guides me along right paths
   for the sake of his name.”

Today, faith is being conveniently portrayed as something which can be easily replaced with other mathematical measurables. I must say that this is a very miserable portrayal of reality. In my opinion, faith and religion are still relevant today and form an intrinsic part of our existence.

I wish to conclude with the words expressed by Professor Woodrow Wilson, 28th President of the United States, "every man sent out from a university should be a man of his nation as well as a man of his time". Evidence of this is the coat of arms and motto of the University of Malta, ‘Ut Fructificemus Deo’ which means ‘Bearing fruit to God’. I am sure that, today, as we are bestowed with this great privilege of graduating from this University, in front of you all, we will rise up to the challenge of being worthy citizens of this small great nation.

Most probably, tomorrow, you would have forgotten all that I said today, as I had forgotten the speech of my first graduation, way back in 2003. However, I sincerely hope you will cherish throughout your lives my departing quotation, penned by Seneca, Roman philosopher … “As is a tale, so is life: not how long it is, but how good it is, is what matters.”

Thank you all very much.