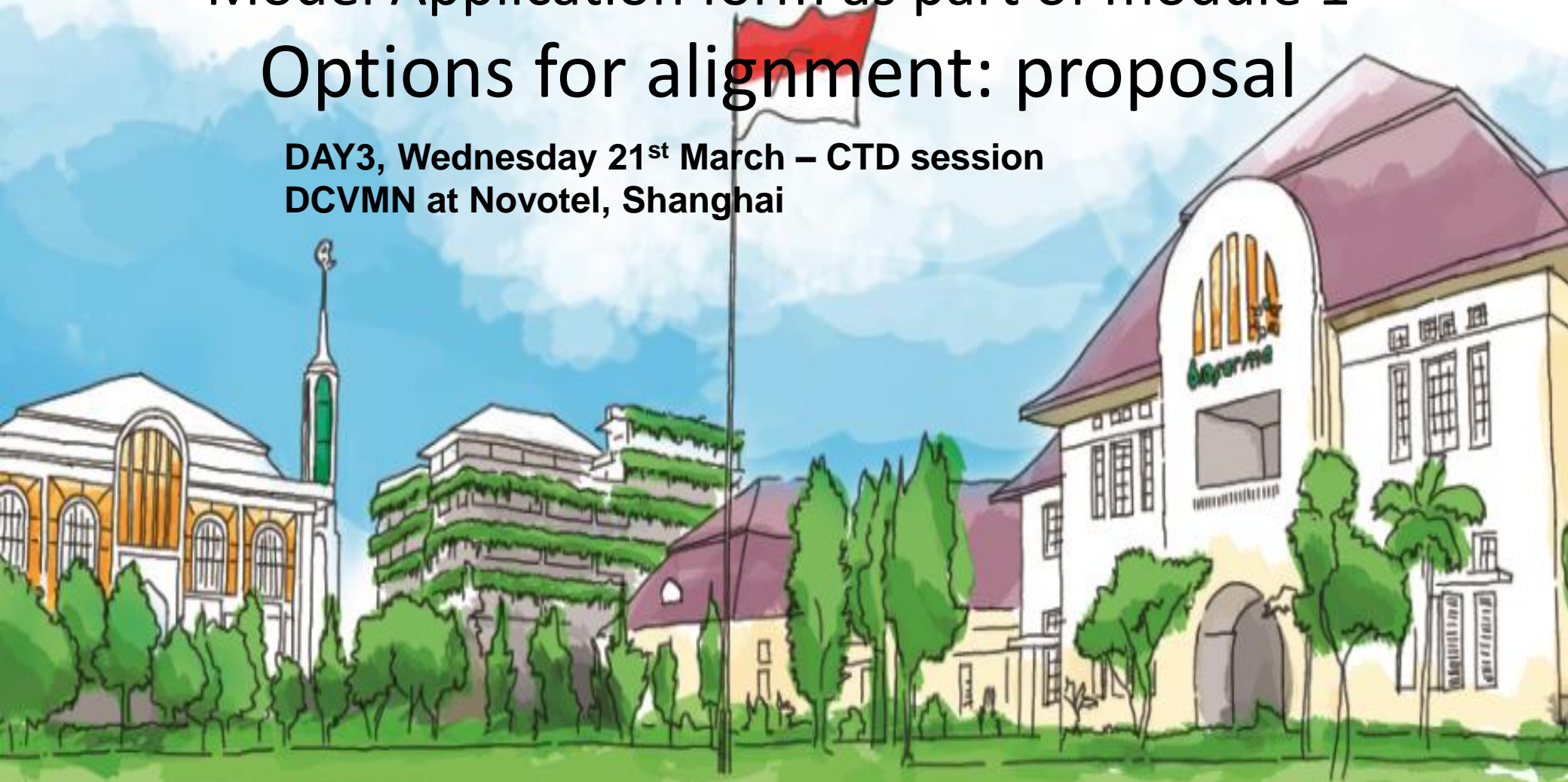


# Model Application form as part of module 1

## Options for alignment: proposal

**DAY3, Wednesday 21<sup>st</sup> March – CTD session  
DCVMN at Novotel, Shanghai**



# ICH CTD

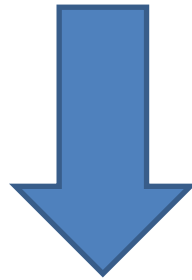
No.	Organization of the Dossier	
1	Module 1	Administrative Information and Prescribing Information
2	Module 2	Common Technical Document Summaries
3	Module 3	Quality
4	Module 4	Nonclinical Study Reports
5	Module 5	Clinical Study Reports

# ICH CTD : Module 1

No.	Organization of Module 1
1	<p data-bbox="182 419 499 544">Sub Module 1.1</p> <p data-bbox="571 419 2011 472">Table of Contents of the Submission Including Module 1</p> <p data-bbox="571 568 1943 665">Note: Contains the overall Table of Contents of the whole CTD (module 1 - 5)</p>
2	<p data-bbox="182 708 499 832">Sub Module 1.2</p> <p data-bbox="571 708 1860 832">Documents Specific to Each Region (for example, <b>application forms</b>, prescribing information)</p> <p data-bbox="571 929 2011 1139">Note: Contains documents specific to each region; for example, application forms or the proposed label for use in the region. The content and format of this module can be specified by the relevant regulatory authorities.</p>

# Application Form

Specific to each country/region



Is there any option for harmonization (?)

# Example of Application Form from Different Countries

No.	Name of Country
1	Ghana
2	Srilanka
3	Egypt
4	<b>G. C. C. STATES</b> (U.A.E, BAHRAIN, SAUDI ARABIA, OMAN, QATAR, KUWAIT, YEMEN)
5	India
6	Irak
7	Bhutan
8	Laos
9	Indonesia

# Application Form from Different Countries



[Indonesia](#)



[Laos](#)



[Bhutan](#)



[Irak](#)



[Srilanka](#)



[India](#)



[GCC State](#)



[Egypt](#)



[Ghana](#)

# Is there any room for harmonization?

## **The Proposed Model**

Thank You