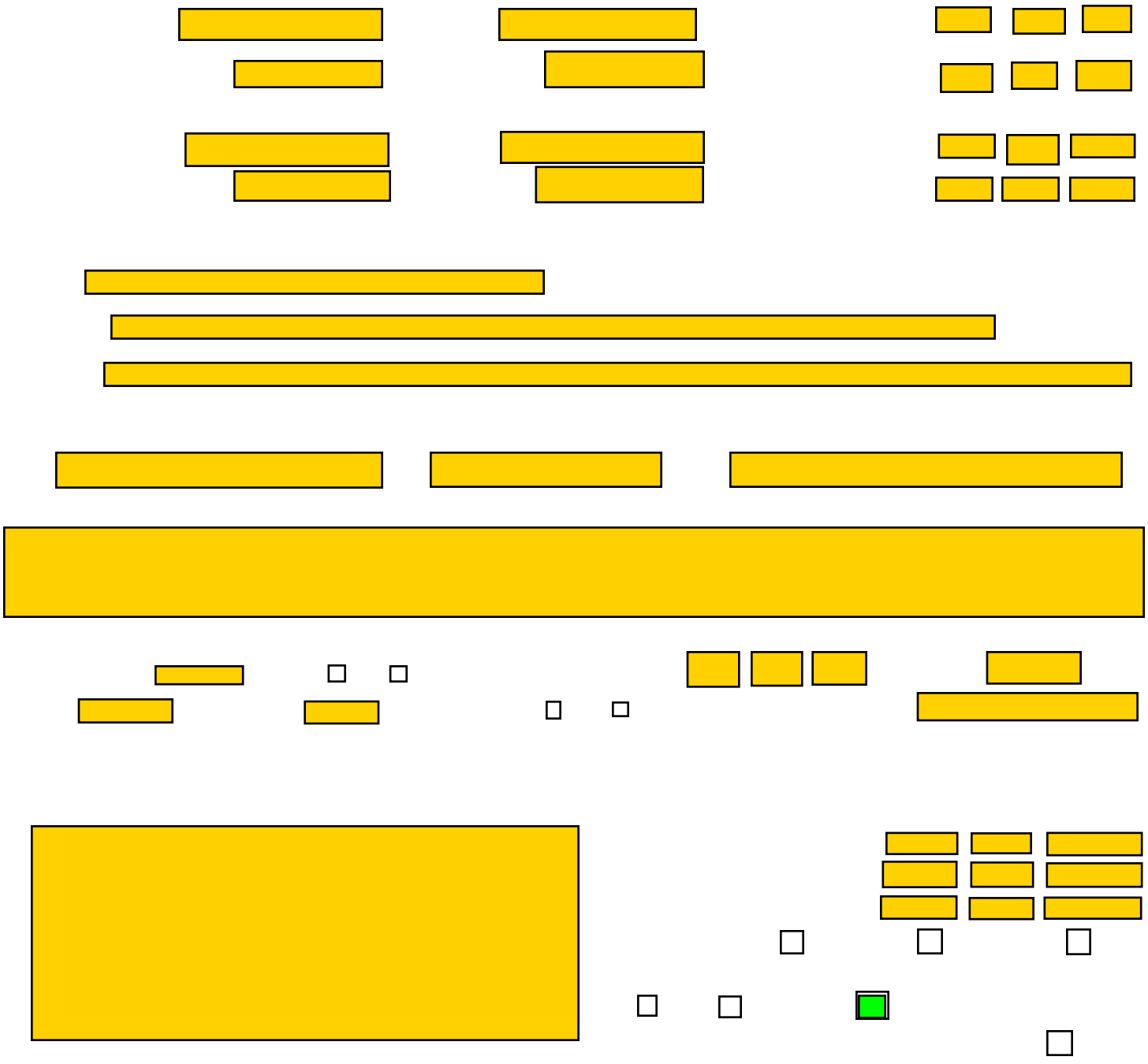

AE FORM

Version Number: V2.0
Effective Date: 10-Nov-2016
This version replaces: V1.0
Parent Document:
Form Title: **Healthcare Providers Adverse Event Reporting Form**

2.	Date of onset (DD/MMM/YY) ___/___/___ Time to onset (D/H/MIN) _____/_____/_____ Resolution date (DD/MMM/YY) _____/_____/_____ Causality Related ☐ Unrelated ☐ Unknown ☐ Did the reaction reappear after reintroduction of drug? Yes ☐ No ☐ Unknown ☐ Not applicable ☐

Action Taken with suspect drug

☐ Product discontinued due to AE ☐ Dose Increased ☐ None
☐ Dose Decreased ☐ Other (please specify):

Patient's Outcome

☐ Recovered without sequelae* Date (DD/MM/YY ___ ___ ___
☐ Recovered with sequelae Date (DD/MM/YY) ___/___/___ Specify sequelae*_____
☐ Ongoing
☐ Improved, but not yet recovered
☐ Death Date of death (DD/MM/YY) ___/___/___ Autopsy: ☐ yes ☐ no
☐ Unknown

Seriousness: Was the event serious or non serious? (please indicate below)

Serious ☐

☐ Patient died
☐ Persistent or significant disability/incapacity
☐ Congenital anomaly/birth defect
☐ Other reasons (please specify):
☐ Initial or prolonged hospitalisation
☐ Life threatening
☐ Other medically important condition

Non Serious ☐

Relevant Medical History (continue on separate sheet if required)

Concomitant disease(s), pregnancy, relevant laboratory results	Known since (i.e. onset date)
1.	
2.	
3.	

Relevant Concomitant drug(s)/Indication (continue on separate sheet if required)	**Total daily dose/route**	**Start date/Therapy duration**
1.		
2.		
3.		

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Additional Comments

*Sequelae: a morbid condition following or occurring as a consequence of another condition or event.