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Global Excellence
Local Expertise

Your Trusted Clinical Research Organization Partner

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Pharmacovigilance

Tigermed-IntelliPV

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COMPREHENSIVE PHARMACOVIGILANCE AND DRUG SAFETY SERVICES FROM A WORLD-CLASS PROVIDER

Tigermed

A Full Suite of PV Services at Your Disposal

Pharmacovigilance Operations for Clinical Trials

- PV system introduction
- Preparation: Review protocol; Review investigator brochure; Review CRF; Draft safety management plan; database setup
- Case management
- Meetings such as safety review committee
- Draft/Review DSUR
- Draft/Review risk management plan

Post-Marketing Pharmacovigilance Operations

- Call center
- Literature search
- Case management, including cases from Health Authority and oversea serious adverse reaction cases
- Draft/Review PSUR
- Draft Annual Report
- Signal detection
- Draft/Review risk management plan

Support Services Outsourcing

- Pharmacovigilance Audits
- Training
- Pharmacovigilance system outsourcing

Data Security

- Tigermed's SOP and relevant guides have been updated according to EU General Data Protection Regulation.
- Procedures for regular testing, assessment and evaluation control objectives.

The Leading Global CRO in China

Team Introduction

5
Offices in China

8
Directors and
Mangers

90+
Employees

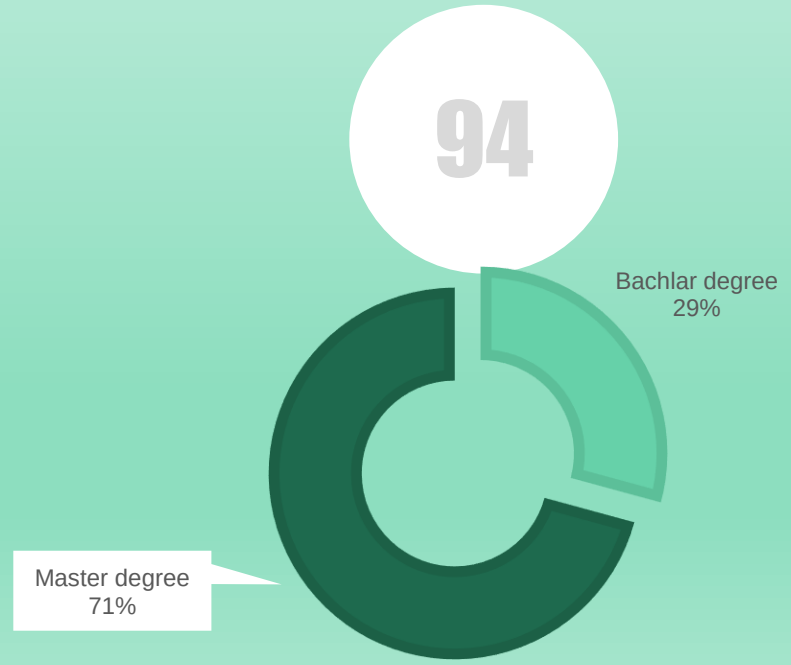
1
MSO Team

*As date of 2020Q1

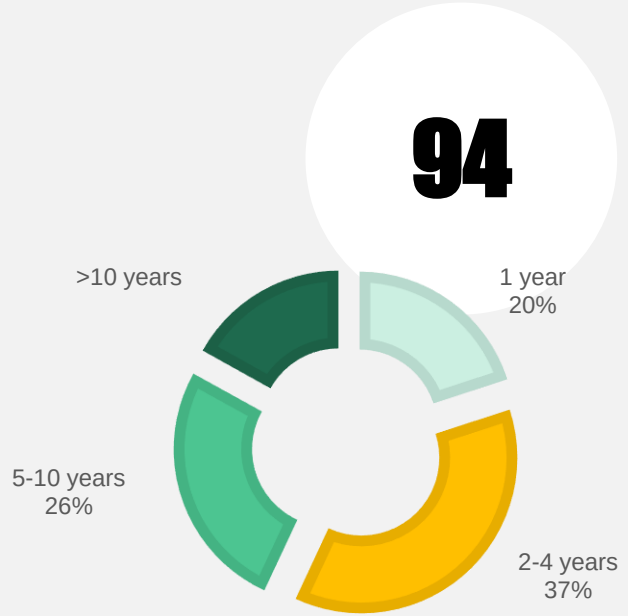
Dedicated and Experienced Staff

Our pharmacovigilance team consists of multilingual MDs and pharmaceutical scientists with broad therapeutic expertise that work according to the latest regulatory requirements

Educational Background



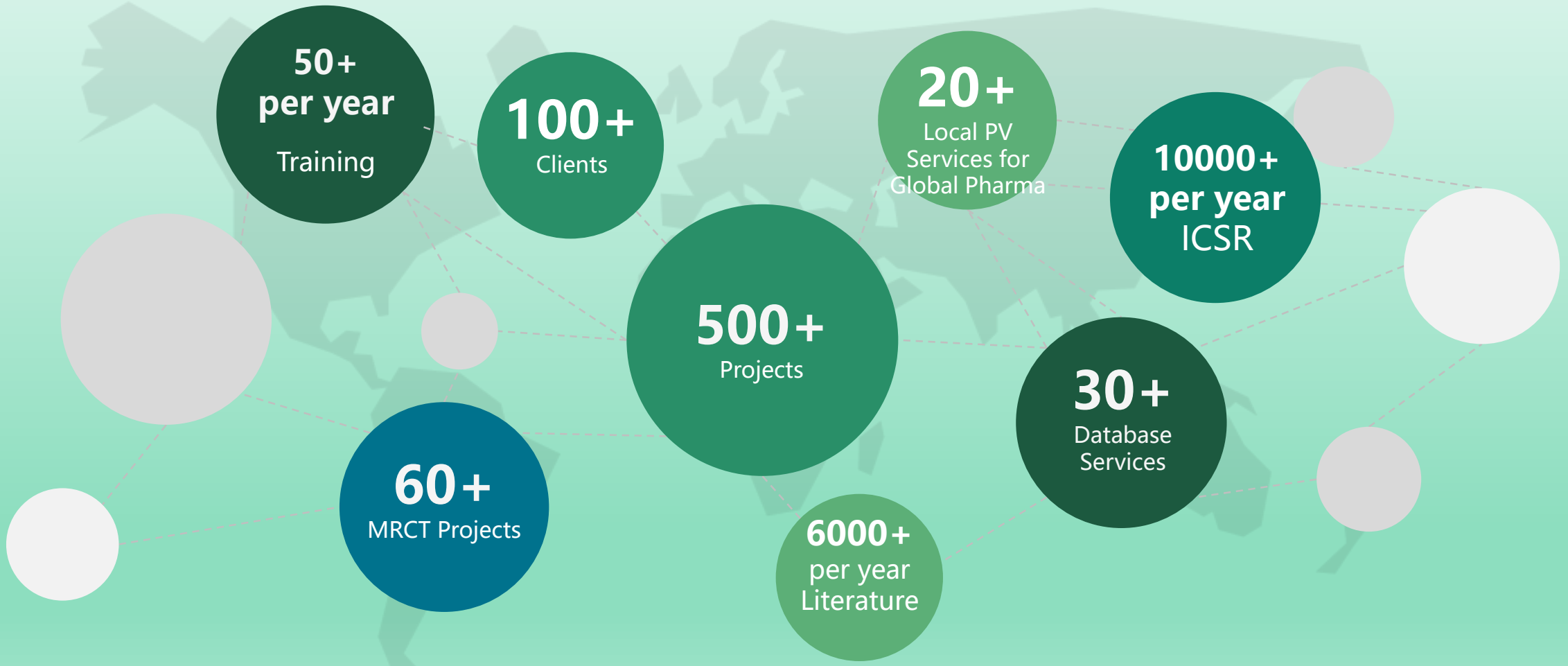
Working Experience



Training

- New staff training and test
- Regulation Training
- SOP Training
- Safety database
- External training
- Project relevant training

Extensive Global Experience



*As date of 2020Q1

Service Scope- Clinical Trial

01

Pre IND

- Review protocol. investigator brochure

02

Study Start Up

- Review CRF， CCI
- Training
- Draft safety management plan
- Set up safety database

03

Study Ongoing

- Case Processing
- Support Reconciliation
- Support SRC, IDMC
- Draft DSUR

04

Pre-NDA

- Review CSR
- Draft Risk management plan

260+
Drug Registration Projects

10+
Post Marketing Projects

*As date of 2020Q1

Service Scope- Post Marketing

All safety data will be protected according to "General Data Protection Regulation"
Safety Data Exchange Agreement will be used for post marketing projects

Source

- **Literature**
  two Chinese databases
  two English database
  weekly search
  original
- **Call Center**
  7*24
  5*8
- **Social Media-Website**

ICSR

- **HA Feedback Report**
- **Oversea SADR**
- **Domestic ADR**

PSUR PBRER

- **Draft**
- **Translation**
- **Review/Proof reading**
- **Submission**
- **Documentation**

Annual Report

- **TIPV Draft-Client Review-Translation**
- **Client draft-Translation-Proof Reading**
- **Submit since 31-MAR-2020**

Signal Detection RMP

- **Evaluate the drug safety regularly**
- **Identify the potential risk, analyze the mechanism and causes of risk occurrence, conduct the post-marketing study initiatively and evaluate the drug risk-benefit continuously**

*As date of 2020Q1

Safety Database

Oracle Argus

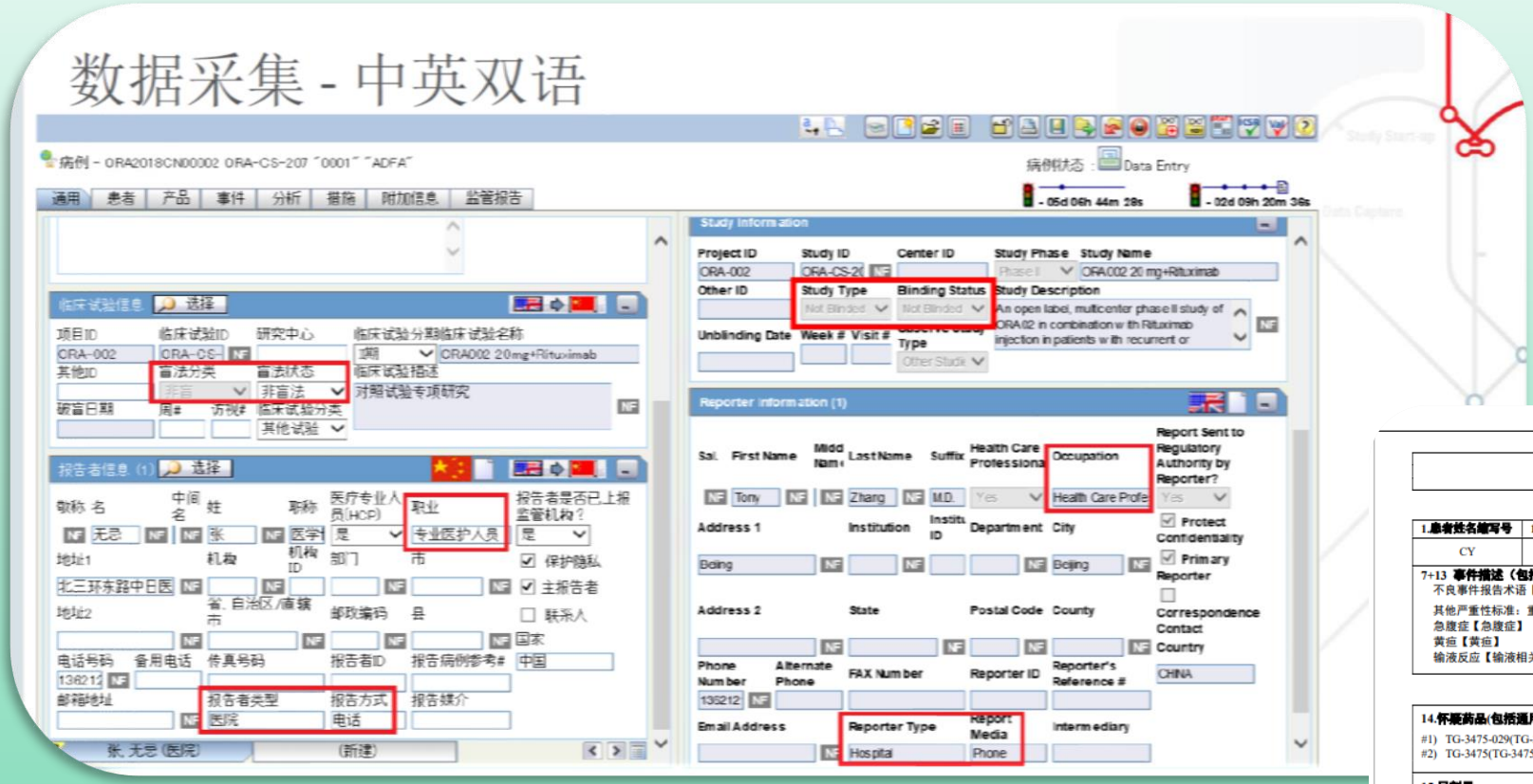
- Business partner of Oracle
- Full audit trial comply with 21 CFR Part 11
- ICH E2B R2/R3
- Bilingual Multi-tenancy
- 130+ projects

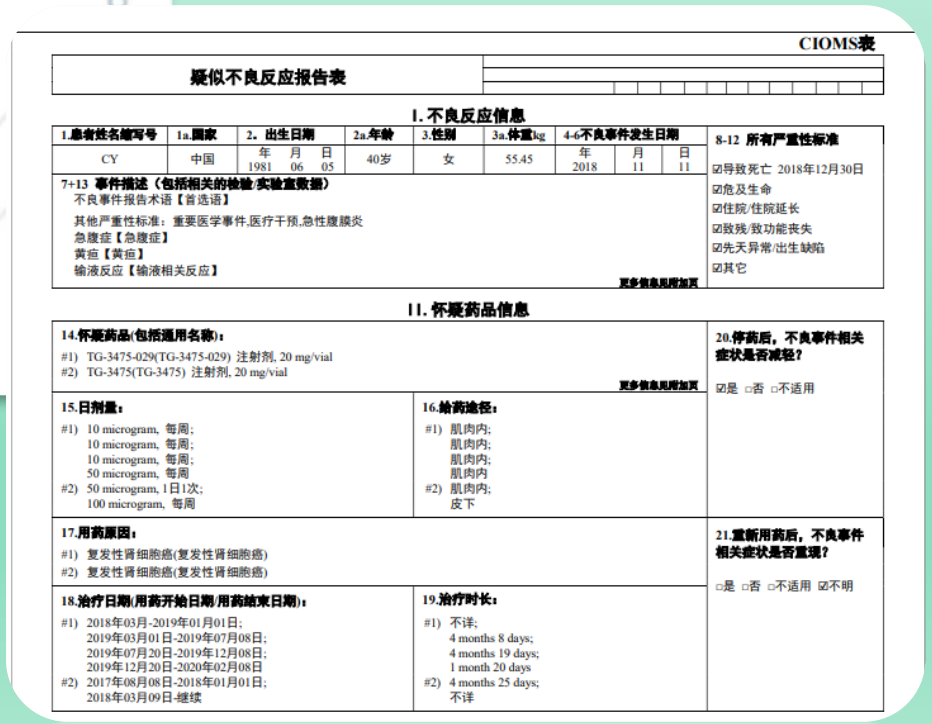
Clinflash Safety

- Full audit trial comply with 21 CFR Part 11
- ICH E2B R3 (data transfer standard)
- 10+ projects

*As date of 2020Q1

Argus





CIOMS表

疑似不良反应报告表

I. 不良反应信息

1.患者姓名缩写号	1a.国家	2. 出生日期	2a.年龄	3.性别	3a.体重kg	4-6不良事件发生日期
CY	中国	年 月 日 1981 06 05	40岁	女	55.45	年 月 日 2018 11 11

7+13 事件描述（包括相关的检验/实验室数据）

不良事件报告术语【首选语】

其他严重性标准：重要医学事件,医疗干预,急性腹膜炎
急腹症【急腹症】
黄疸【黄疸】
输液反应【输液相关反应】

更多信息见附加页

8-12 所有严重性标准

☑导致死亡 2018年12月30日
☑危及生命
☑住院/住院延长
☑致残/致功能丧失
☑先天异常/出生缺陷
☑其它

II. 怀疑药品信息

14.怀疑药品(包括通用名称):

#1) TG-3475-029(TG-3475-029) 注射剂, 20 mg/vial
#2) TG-3475(TG-3475) 注射剂, 20 mg/vial

更多信息见附加页

20.停药后，不良事件相关症状是否减轻?

☑是 □否 □不适用

15.日剂量:

#1) 10 microgram, 每周;
10 microgram, 每周;
10 microgram, 每周;
50 microgram, 每周
#2) 50 microgram, 1日1次;
100 microgram, 每周

16.给药途径:

#1) 肌肉内;
肌肉内;
肌肉内;
肌肉内
#2) 肌肉内;
皮下

17.用药原因:

#1) 复发性肾细胞癌(复发性肾细胞癌)
#2) 复发性肾细胞癌(复发性肾细胞癌)

21.重新用药后，不良事件相关症状是否重现?

□是 □否 □不适用 ☑不明

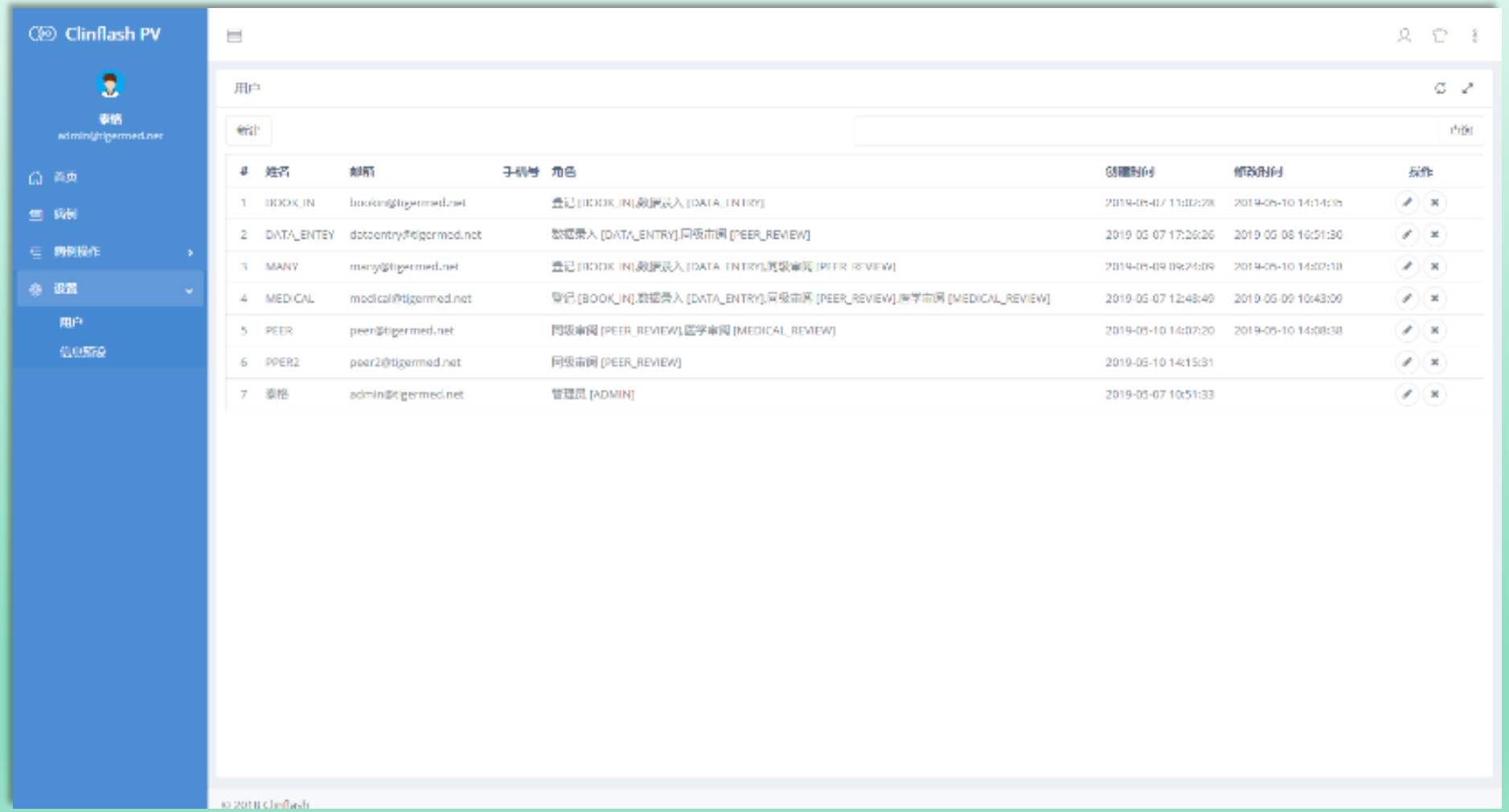
18.治疗日期(用药开始日期/用药结束日期):

#1) 2018年03月-2019年01月01日;
2019年03月01日-2019年07月08日;
2019年07月20日-2019年12月08日;
2019年12月20日-2020年02月08日
#2) 2017年08月08日-2018年01月01日;
2018年03月09日-继续

19.治疗时长:

#1) 不详;
4 months 8 days;
4 months 19 days;
1 month 20 days
#2) 4 months 25 days;
不详

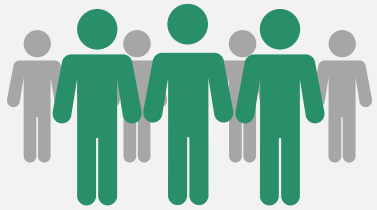
Clinflash Safety



Project Management

Kick-off Meeting
Regular Meeting

- Communication
- Process Report about compliance, quality and other information requested



5+
Professional experts, including SPM+DSA

Set up safety database

Execute all terms in contract

PV Team Set up

SMP/SDEA

Training

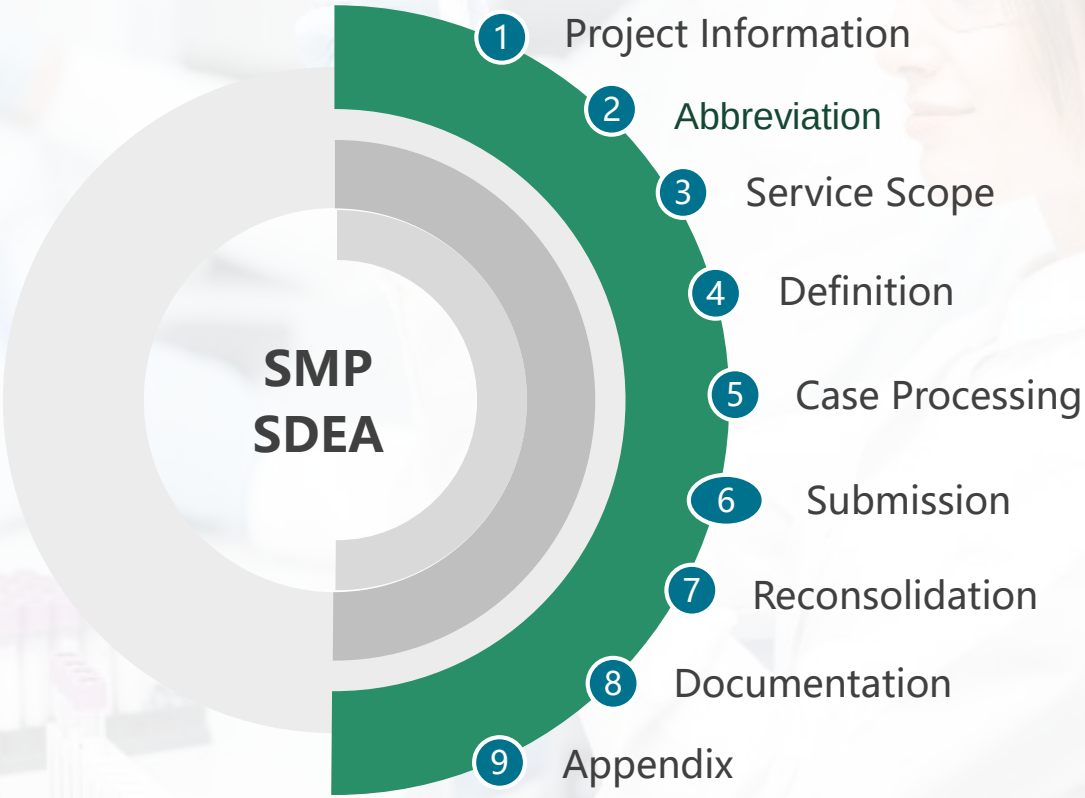
- SOP training provided by client
- Ad-hoc training per business need
- Other system/database training

*As date of 2020Q1

Timeline

	Items	Timeline	Duration
SMP/SDEA	Draft	6 weeks after signing the contract	2 weeks
	First round review	4 weeks after signing the contract	2 weeks
	Update and second round review	1 weeks after signing the contract	1 week
	Finalization and signature	1 weeks after signing the contract	1 week
Safety database	Information collection	6 weeks after signing the contract	2 weeks
	Project setup	4 weeks after signing the contract	2 weeks
	Go live	2 weeks before executing ICSR relevant terms in contract	NA

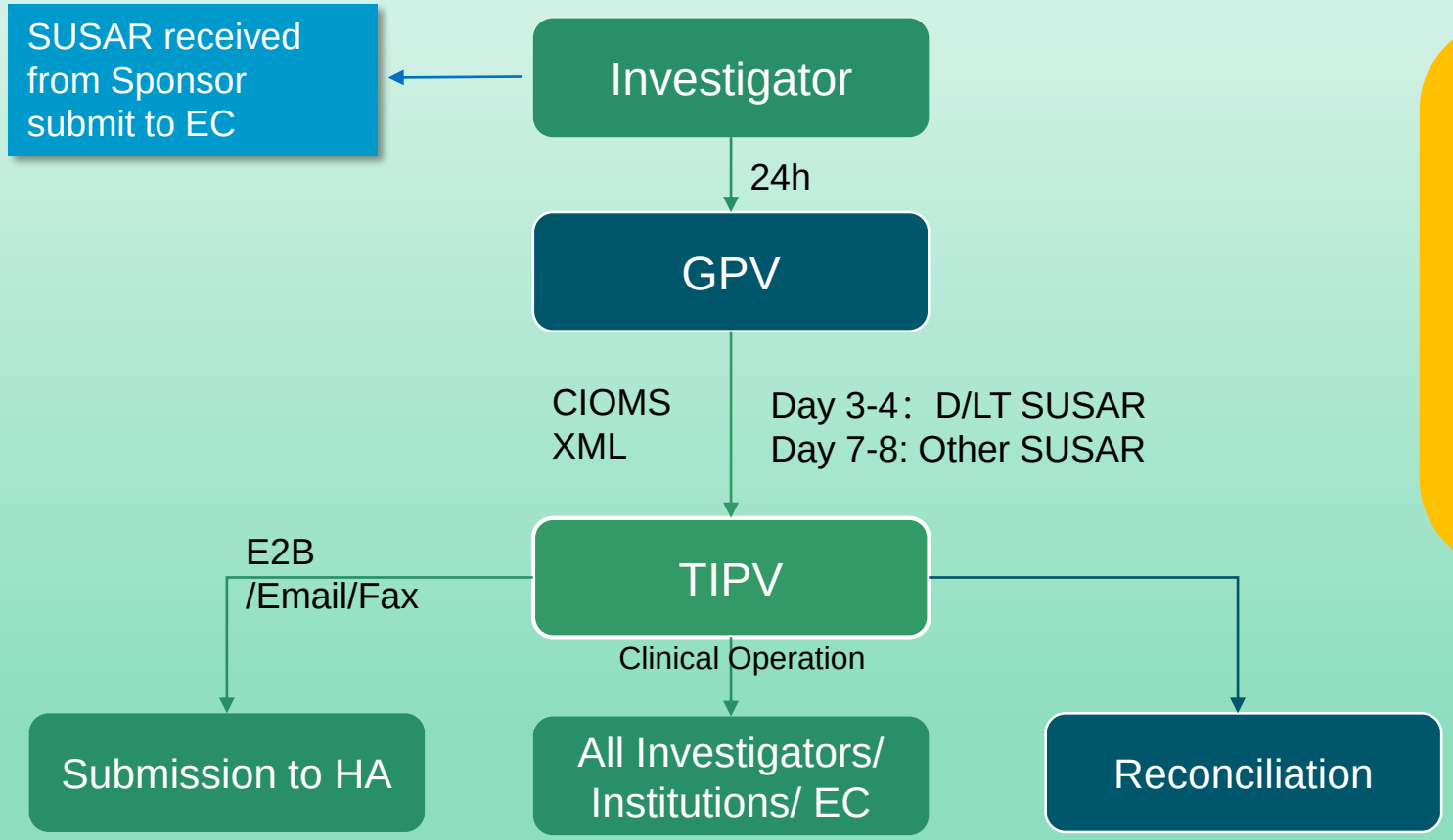
SMP/SDEA



Holiday Arrangement

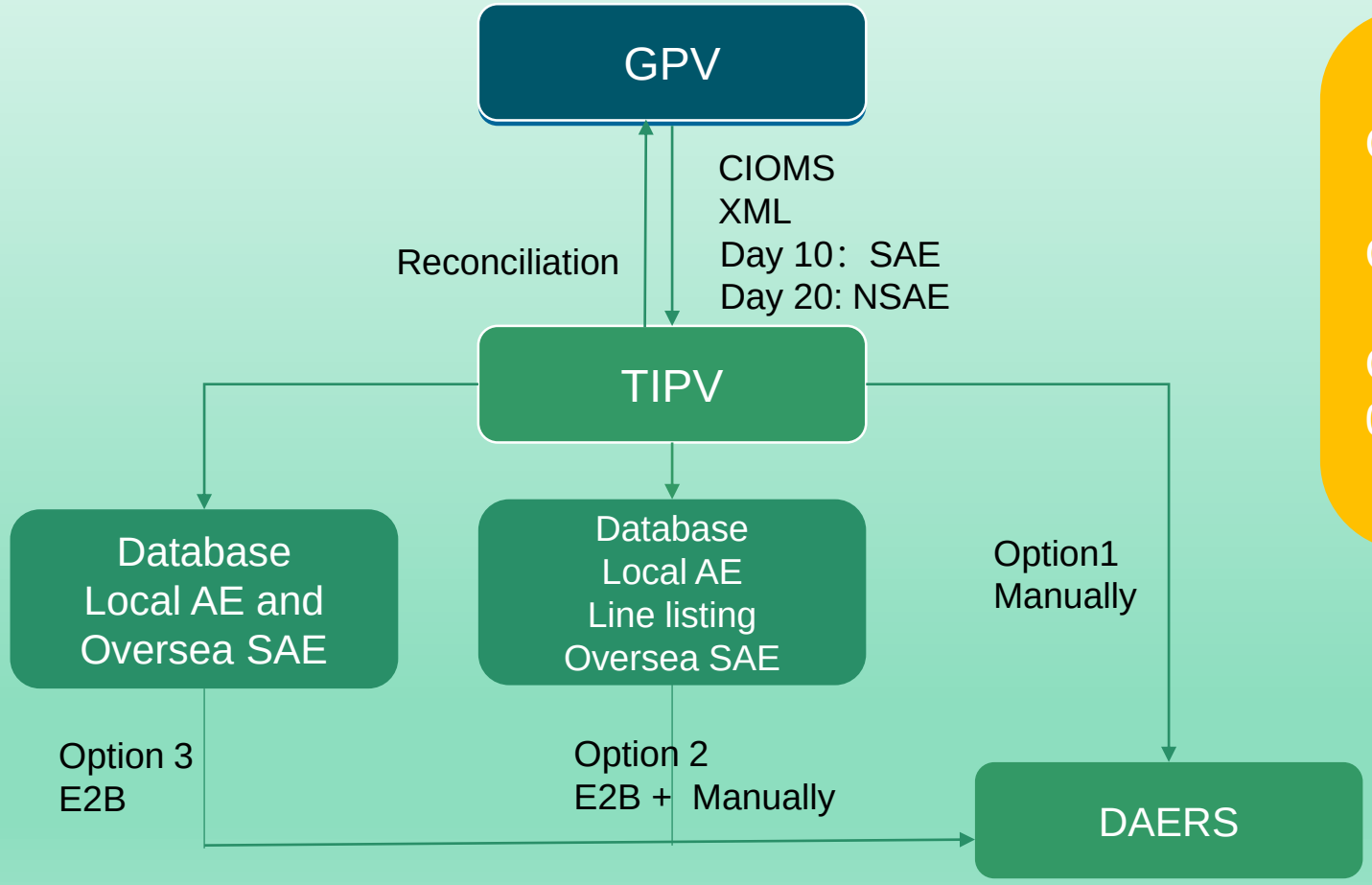
1. To ensure compliance, someone will be on duty for more than 3 days holiday;
2. At least 1 DSA and 1 backup DSA for each project;
3. Due case reminder will be sent to DSA, to make sure all due cases will be closed before holiday.

Proposal-Clinical Trial



Sites' requirements: D/LT SUSAR should be submitted to investigator/Institution/ EC with in 7 days and other SUSAR reports within 15 days.

Proposal-Post Marketing



Option 1： Now-01-JUL-2022

Option 2： Now-01-JUL-2022

Option 3： Mandatory after 01-JUL-2022

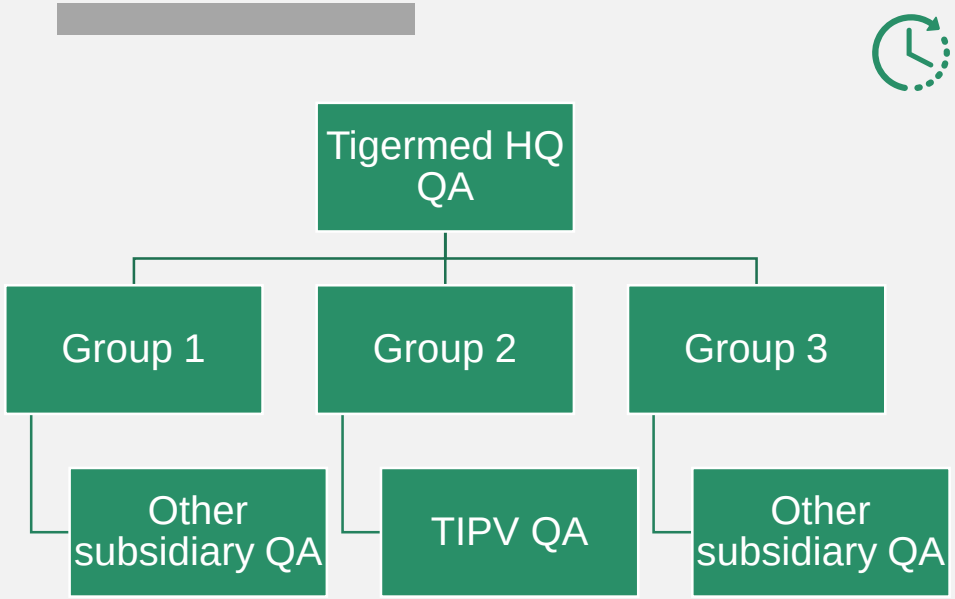
ICSR Case Processing

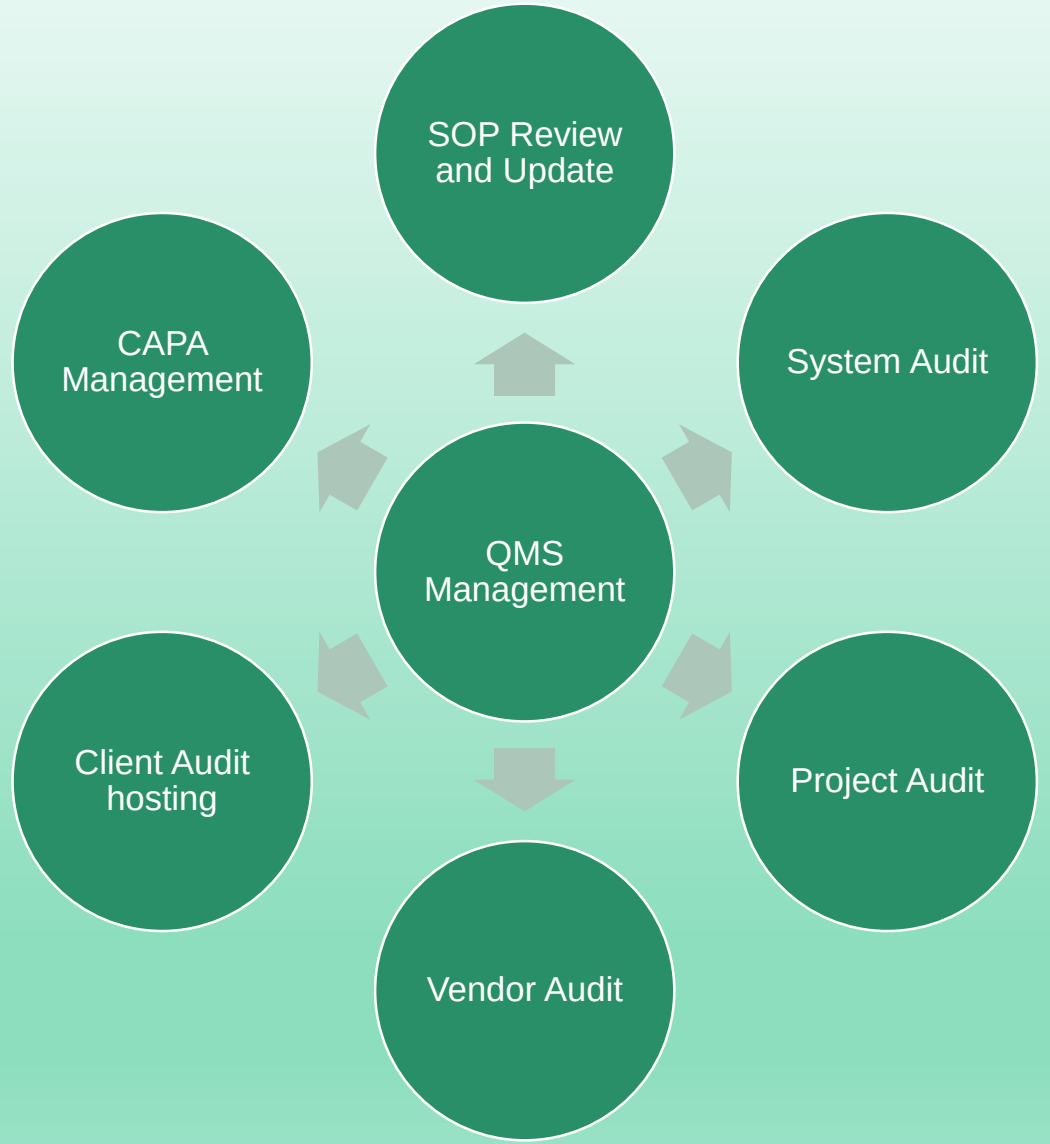
- Case Receipt - mailbox
- Case Intake and triage
- Data Entry
- Quality Control
- Medical Review (operational)
- Client Approval (operational)
- Submission

- MedDRA Coding： Medical History, Concurrent Condition, Lab, Indication, Adverse Event
- WHO Drug: Drug/Device/Vaccine
- Listedness
- Seriousness
- Causality
- Case Analysis : Narrative, Company Comment

Compliance **Quality**

Quality Management System





*As date of 2020Q1

SOP List

泰格益坦现行版SOP清单

Tigermed-IntelliPV Active SOP List

版本日期 Version Date 9-Apr-20

文件编号 Document No.	文件名称 Document Title	版本日期 Version Date	生效日期 Effective Date	适用范围 Applicable Scope
SOP-PV-01	Clinical SAE Reporting Requirement and Procedure	8.1.0 9 Mar 2020	9 Apr 2020	Tigermed
SOP-PV-02	Post-marketing Adverse Event Reporting	8.0 09 Mar 2020	9 Apr 2020	Tigermed-IntelliPV
SOP-PV-08	Argus Safety Set-up Management	2.0 09 Mar 2020	9 Apr 2020	Tigermed-IntelliPV
SOP-PV-09	Documentation and Archiving Process	2.0 23 Jul 2019	23 Aug 2019	Tigermed-IntelliPV
SOP-PV-10	Serious Adverse Event Reconciliation between Clinical Database and Safety database	2.1.0 9 Mar 2020	9 Apr 2020	Tigermed
SOP-PV-14	Case Receipt, Intake and Triage	1.1.0 9 Mar 2020	9 Apr 2020	Tigermed-IntelliPV
SOP-PV-15	Case Processing Guidance	1.0 28 Jan 2019	28 Feb 2019	Tigermed-IntelliPV
SOP-PV-16	Project Handover Process	1.0 28 Jan 2019	28 Feb 2019	Tigermed-IntelliPV
SOP-PV-17	ICSR Quality Control Process	1.1 23 Jul 2019	23 Aug 2019	Tigermed-IntelliPV
SOP-PV-18	Medical Assessment	1.0 28 Jan 2019	28 Feb 2019	Tigermed-IntelliPV
SOP-PV-19	PV Inspection	1.1.0 9 Mar 2020	9 Apr 2020	Tigermed-IntelliPV
SOP-PV-20	MedDRA Coding Conventions	1.0 27 May 2019	27 Jun 2019	Tigermed-IntelliPV
SOP-PV-21	Analysis of Similar Events	1.0 27 May 2019	27 Jun 2019	Tigermed-IntelliPV
SOP-PV-22	Narrative Writing	1.0 27 May 2019	27 Jun 2019	Tigermed-IntelliPV
SOP-PV-23	Processing of Serious Adverse Event Retrieval From Safety Database	1.0 27 May 2019	27 Jun 2019	Tigermed-IntelliPV
SOP-PV-24	Obtaining Follow-up Information	1.0 27 May 2019	27 Jun 2019	Tigermed-IntelliPV
SOP-PV-25	Cluster Adverse Drug Events Handling Procedure	1.0 27 May 2019	27 Jun 2019	Tigermed-IntelliPV
SOP-PV-26	Serious Overseas Adverse Drug Reactions Handling Procedure	1.0 27 May 2019	27 Jun 2019	Tigermed-IntelliPV
SOP-PV-27	Pharmacovigilance Business Continuity Plan	1.1.0 9 Mar 2020	9 Apr 2020	Tigermed-IntelliPV
SOP-PV-28	Protect Data Privacy in Individual Case Safety Report (ICSR) Reporting	1.0 27 May 2019	27 Jun 2019	Tigermed-IntelliPV
SOP-PV-29	Literature Screening	1.1.0 9 Mar 2020	9 Apr 2020	Tigermed-IntelliPV
SOP-PV-30	Preparation of Development Safety Update Report	1.1.0 9 Mar 2020	9 Apr 2020	Tigermed-IntelliPV
SOP-PV-31	Reconciliation of Individual Case Safety Report (ICSR)	1.0.0 9 Mar 2020	9 Apr 2020	Tigermed-IntelliPV
SOP-PV-32	Case Correction	1.0.0 9 Mar 2020	9 Apr 2020	Tigermed-IntelliPV
SOP-PV-33	Periodic Safety Update Reports (PSUR) and Periodic Benefit-Risk Evaluation Report (PBRER) Preparation and Submission Procedure	1.0.0 9 Mar 2020	9 Apr 2020	Tigermed-IntelliPV

Handling Emergency Events and BCP

TIPV's big team scale and different locations could ensure back-up of each sites when emergency occurred.

PV BCP SOP

- Periodic Capacity Assessment to ensure enough FTE
- Deal with Unusual amount of cases
- Testing of BCP, call center, VPN connection, Mailbox, Fax, etc.
- IT Helpdesk support

Emergency Example

- Covid-19 since Spring Festival
- Work from home when office not available
- Other sites support EMS submission to NMPA for Wuhan colleague

Global Excellence Local Expertise

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