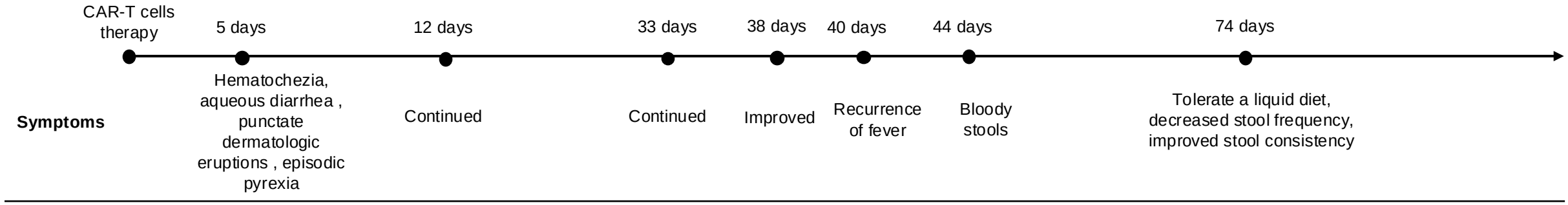
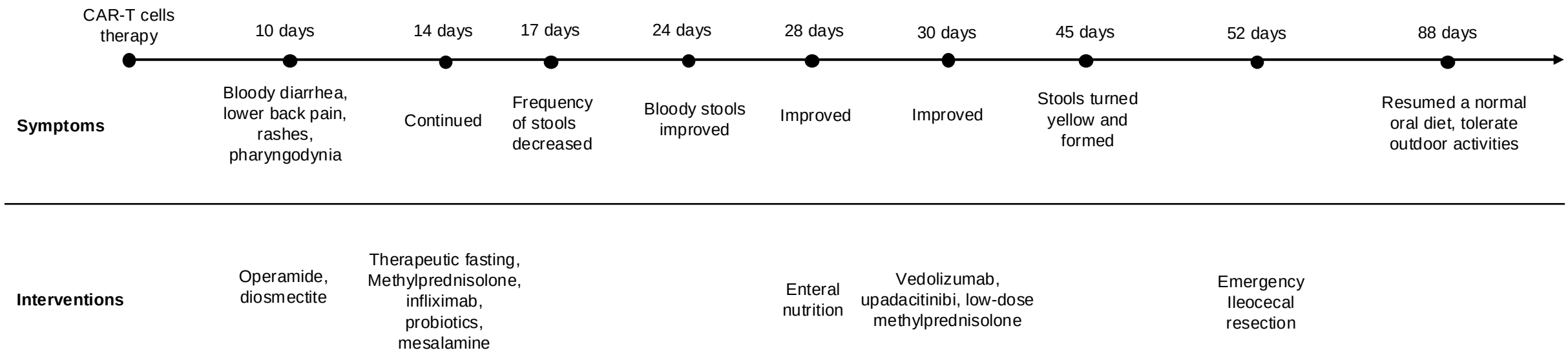
Timeline of Symptoms and Interventions in Relation to CAR-T cells infusion

Case 1



Case 2



CARE case report guidelines

CARE Checklist of information to include when writing a case report

Topic	Item	Checklist item description	Reported on Line
Title	**1**	The diagnosis or intervention of primary focus followed by the words "case report"	✓
Key Words	**2**	2 to 5 key words that identify diagnoses or interventions in this case report, including "case report"	✓
Abstract (no references)	**3a**	Introduction: What is unique about this case and what does it add to the scientific literature?	✓
	3b	Main symptoms and/or important clinical findings	✓
	3c	The main diagnoses, therapeutic interventions, and outcomes	✓
	3d	Conclusion—What is the main "take-away" lesson(s) from this case?	✓
Introduction	**4**	One or two paragraphs summarizing why this case is unique (**may include references**)	✓
Patient Information	**5a**	De-identified patient specific information.	✓
	5b	Primary concerns and symptoms of the patient.	✓
	5c	Medical, family, and psycho-social history including relevant genetic information	✓
	5d	Relevant past interventions with outcomes	✓
Clinical Findings	**6**	Describe significant physical examination (PE) and important clinical findings.	✓
Timeline	**7**	Historical and current information from this episode of care organized as a timeline	✓
Diagnostic Assessment	**8a**	Diagnostic testing (such as PE, laboratory testing, imaging, surveys).	✓
	8b	Diagnostic challenges (such as access to testing, financial, or cultural)	✓
	8c	Diagnosis (including other diagnoses considered)	✓
	8d	Prognosis (such as staging in oncology) where applicable	✓
Therapeutic Intervention	**9a**	Types of therapeutic intervention (such as pharmacologic, surgical, preventive, self-care)	✓
	9b	Administration of therapeutic intervention (such as dosage, strength, duration)	✓
	9c	Changes in therapeutic intervention (with rationale)	✓
Follow-up and Outcomes	**10a**	Clinician and patient-assessed outcomes (if available)	✓
	10b	Important follow-up diagnostic and other test results	✓
	10c	Intervention adherence and tolerability (How was this assessed?)	✓
	10d	Adverse and unanticipated events	✓
Discussion	**11a**	A scientific discussion of the strengths AND limitations associated with this case report	✓
	11b	Discussion of the relevant medical literature **with references**.	✓
	11c	The scientific rationale for any conclusions (including assessment of possible causes)	✓
	11d	The primary "take-away" lessons of this case report (without references) in a one paragraph conclusion	✓
Patient Perspective	**12**	The patient should share their perspective in one to two paragraphs on the treatment(s) they received	✓
Informed Consent	**13**	Did the patient give informed consent? Please provide if requested	**Yes** ✓ **No** ☐

浙江大学医学院附属第一医院 IIT 伦理审查委员会伦理审查批件

Approval Letter of Clinical Research Ethics Committee of the First Affiliated Hospital, Zhejiang University School of Medicine

受理号：IIT20240194A　　批件号Reference Number：浙大一院伦审2024研第0133号-快

项目名称 Study Title	两例靶向 CEA 的 CAR-T 治疗后的严重肠炎 Two cases of severe colitis after CEA-directed CAR T therapy		
组长单位 LeadSite	浙江大学附属第一医院 The First Affiliated Hospital, Zhejiang University School of Medicine	科室 Department	消化内科 Gastroenterology
主要研究者 PI	沈哲 Zhe Shen	协调研究者 SubI	俞陌桑 Mosang Yu
审查文件 Documents Review	☑临床研究伦理审查申请表 ☑临床研究方案（版本号 1.0 ，版本日期 2024.02.03 ） ☑免除知情同意书申请表		

审查意见 Evaluation Comments：

☑批准 Approval　□修改后批准 Conditional Approval　□修改后再审 Re-submission

□暂停或者终止研究 Suspended or Termination　□不批准 Disapproval

IIT 伦理审查委员会

主任或副主任签名 Signature of Chairman：

日期 Date：2024 年 02 月 05 日

浙江大学医学院附属第一医院 IIT 伦理审查委员会（盖章）

Clinical Research Ethics Committee of the First Affiliated Hospital, Zhejiang University School of Medicine

备注:1. 研究者应遵循伦理委员会批准的方案执行，实施过程应符合赫尔辛基宣言的原则。

2. 在试验实施过程中，对研究方案和知情同意等相关文件所作的任何修改，均需得到伦理委员会审查同意后方可实施。

3. 发生严重不良事件及可能影响风险受益比的任何事件和新信息须及时报告本院伦理委员会。

4. 接受伦理委员会持续审查的项目，请在到期前1个月（无论试验开始与否）提出再次审查的申请。

5. 如有不依从/违背方案或暂停/提前终止的试验项目，应及时以书面文件报告本院伦理委员会；临床试验结束后，须及时向伦理委员会提交结题报告。

6. 本研究应自批准之日起一年内实施，如试验逾期未实施自行废止。