



**Alpan Farma**

**Clinical Trials Supply Solutions [CTSS]**  
***Mobile Nursing Services***

# About us

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- ▶ **ALPAN Farma** – with capabilities and expertise in CRO services such as clinical trial design, clinical trial project management, study coordinator & CRA resourcing and Regulatory Affairs consultancy services inc. risk assessment and mitigation strategies.
- ▶ With substantial therapeutic and study experience in both early and late phase multinational trials.
- ▶ Offering flexible and effective services for our customers to save time and money whilst facilitating the achievement of project milestones objectives
  - ▶ Operating in multiple locations in Turkey and experience in working with the majority of small to large Pharma, Biotech and CRO companies
  - ▶ Extended its services to Home Nursing in Jan.2020 under the Alpan Farma CTSS and became the 1<sup>st</sup> local provider of Home Nurse support solutions for the clinical trials industry in Turkey region

# About us

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2007

Established in Kayseri Erciyes Teknopark, Turkey

2019

Opening of Istanbul Sisli Bomonti Branch

2020

ALPAN Farma CTSS  
to provide Home Nursing



# General summary:

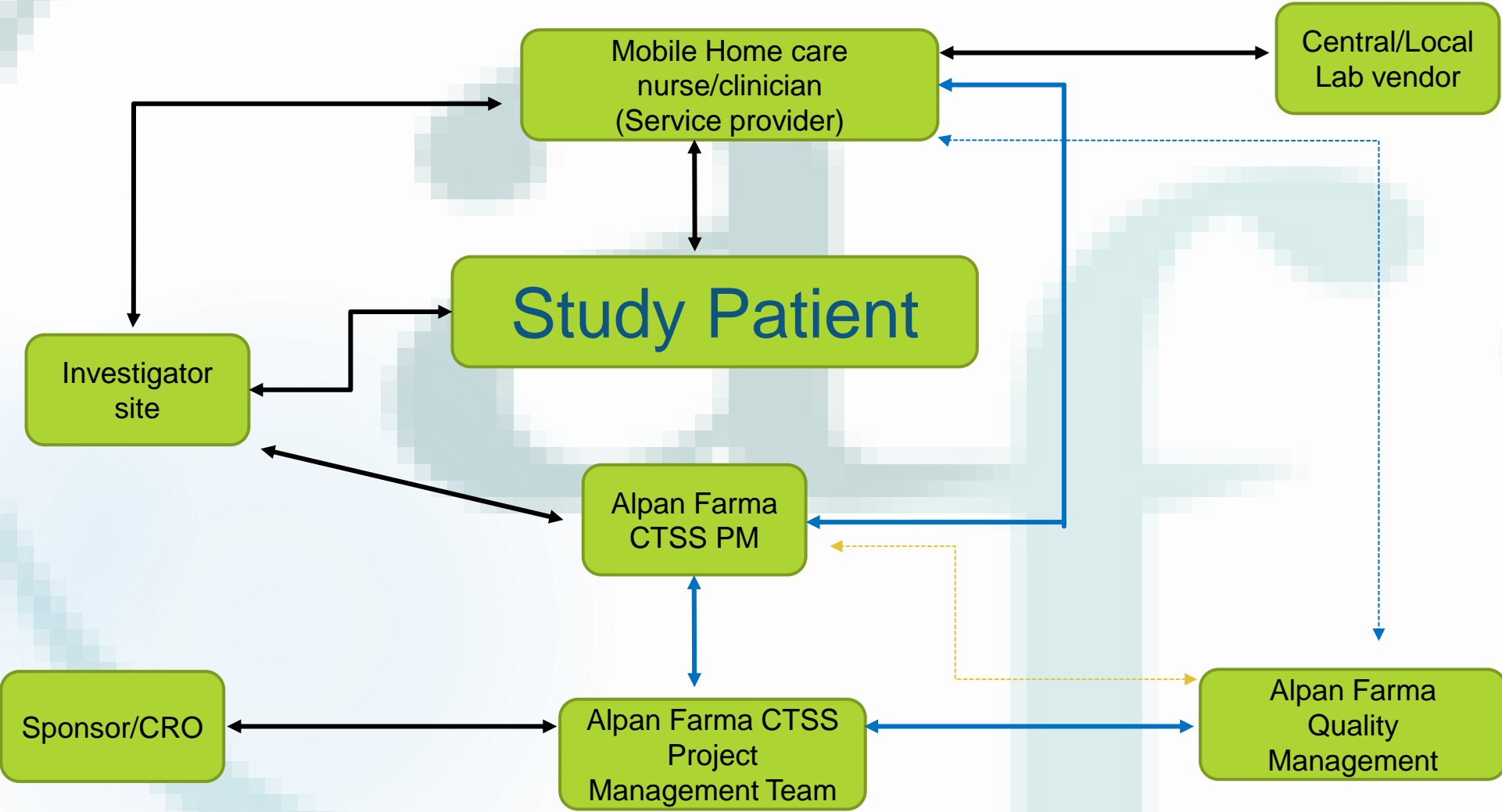
- Centralize management for services
- Primary and Back-up Project Managers available 24/7
- Ambulant/Mobile care services with Nurse/Clinician support available– both primary and back-up for each patient (Adults/pediatrics)
- Study visits available: If requested by the study Sponsor/CRO- can be provided
  - SoA e.g. if requested, blood sampling for PK), support can be given for the packaging and shipping to Central/Local Lab.
- Upon request, SC and CRA resourcing is also available

# General summary:

- Our services can include but not limited to:
  - Scheduling of Home visits\*
  - Conducting study assessments such as vital signs, changes in concomitant medications and signs/symptoms, medical history
  - Peripheral blood draws
  - Central line draws (if required)- TBD
- Source documentation/communications

\* *Patient Transfer to the hospital when necessary*

# Services provided by Alpan Farma CTSS





# Mobile Nursing- Process Pathway

1. Completed & signed Service Request Form will be sent to Alpan Farma CTSS by Investigator Site (min. 1-2 weeks lead time).
2. Alpan Farma CTSS Project Manager will confirm receipt of the request
3. Alpan Farma CTSS will select and arrange for the study support team\* for the execution of requested services (service can be defined as upfront for each site). Prior to the provision of requested service study support team member\* will provide the followings to investigator site: CV, credentials, training documentation and signed site delegation form
4. Home nurse will contact patient and schedule time and date for visit in accordance with the Service Request Form. Service Provider obtains the biologic samples, conducts assessments and/or administers study drug, as ordered by the PI in the Service Request Form, and completes Source Documentation.

\* *Home nurse*

# Mobile Nursing- Process Pathway (cont.)

5. Home nurse processes, packages and arranges for courier delivery of samples to the Central/Local Lab.
6. Central/Local lab receives and analyzes samples and provides results directly to the investigator site (via their web-platform)
7. Home nurse sends copy of visit Source Document to the responsible Alpan Farma CTSS PM team for further Quality assessment
8. Alpan Farma CTSS forwards a copy of approved visit Source Documents to the Investigator site promptly after each visit (usually within 48 hours of visit).



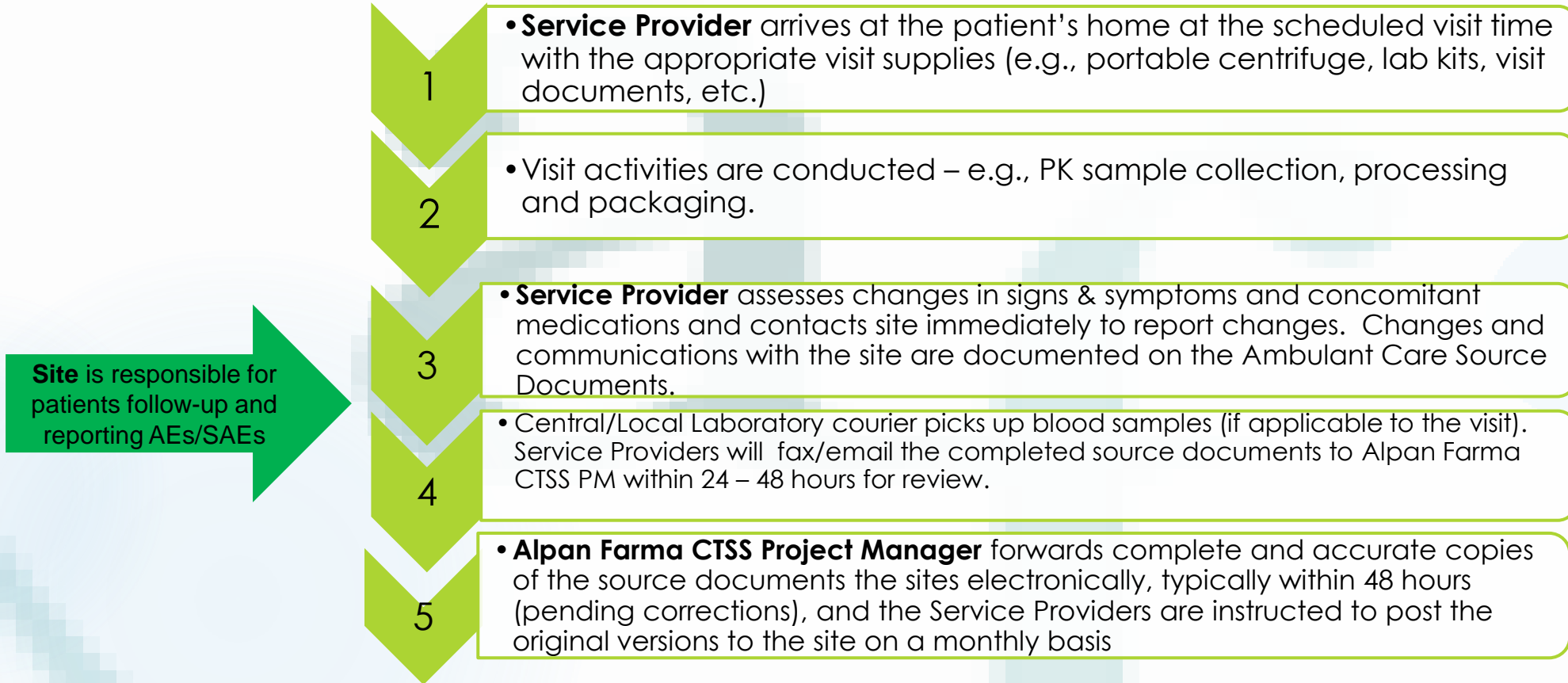
# Mobile Nursing- Process Pathway (cont.)

9. Alpan Farma CTSS subsequently sends original visit Source Documents to the Investigator Site via regular mail/courier
10. Alpan Farma CTSS PM provide status updates and invoices to Sponsor/Delegate at agreed timelines for services rendered. ***Our services are complimentary to the sites and patients***
11. Sponsor/Delegate will need to provide any relevant study status updates to Alpan Farma CTSS team if/when required in timely manner
12. Each Service Provider (i.e. Nurse/Clinician) will complete the Site Delegation log following their study training by Alpan Farma CTSS Project Manager

# Mobile Nursing- Process Pathway (cont.)

- 13. The PI will delegate specific responsibilities to each Service Provider in advance to the provision of their services
- 14. The original Site Delegation log signed by the Home Nurse will be provided to the site for completion by the PI.

# Mobile Nursing- Process Pathway (services provided by SP)



# CTSS Mobile Nursing Service - Team

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<p><b>CTSS Project Manager</b></p> <p>Dr. Özgür Soydan</p> <p><i>ozgur@alpanfarma.com</i> +90 533 448 9343</p>	<p><b>CTSS Project Manager (Back-up)</b></p> <p>Elif Erenmemişoğlu</p> <p><i>elif@alpanfarma.com</i> +90 536 216 2721</p>	<p><b>CTSS Site Support Team Manager</b></p> <p>Gönül Osmanoğlu</p> <p><i>gonul@alpanfarma.com</i> +90 532 443 6963</p>
<p><b>Alpan Farma CTSS Project Team</b> <i>info.ctts.pm@alpanfarma.com</i></p>		
<p><b>Alpan Farma &amp; Alpan Farma CTSS Company Director</b></p> <p>Prof. Dr. Aydın Erenmemişoğlu</p> <p><i>aydin@alpanfarma.com</i> +90 532 551 0082</p>		

# Alpan Farma CTSS: Mobile Nursing - Timelines

Week	Activity
Weeks 1-2	<ul style="list-style-type: none"><li>• Initial kick-off teleconference call(s) with Sponsor/Delegate Project team and vendor(s) (e.g., central lab) if required</li><li>• Development of Ambulant Care Training Manual</li><li>• Development of Service Request Forms</li><li>• Development of Ambulant Care Source Document</li><li>• Set up of study trackers/central files</li><li>• Meeting ADI log/Risk Log (xls)</li></ul>
<ul style="list-style-type: none"><li>• Week 3-4</li></ul>	<ul style="list-style-type: none"><li>• Finalize Ambulant Care Training Manual</li><li>• Internal project training</li><li>• Begin identification/qualification/training of local ambulant care Service Providers</li></ul>

# Alpan Farma CTSS: Mobile Nursing – Timelines *(cont.)*

Week	Activity
Week 4+	<ul style="list-style-type: none"><li>• Provide sites (e.g. SC) with F2F or virtual orientation to Alpan Farma CTSS activities/services (upon request)</li></ul>
Week 5+	<ul style="list-style-type: none"><li>• Provide requested ambulant care visits</li><li>• Provide regular status updates</li><li>• Provide monthly invoices</li></ul>

# Alpan Farma CTSS: Mobile Nursing - Materials

- Documents to Alpan Farma CTSS
  - Protocol
  - Lab Manual
  - IMPD (if possible)
  - IP Manual
  - Any other relevant



# Alpan Farma CTSS: Mobile Nursing - Materials *(cont.)*

- Documents to Sponsor/Delegate for Review
  - Service Request Form (SRF)
  - Source Documents (if requested)
  - SP Training Manual
  - Finalize Documents
- Identify FPFV site locations and timelines

# Contact:

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- ▶ Please contact us for Alpan Farma & Alpan Farma CTSS to discuss where we can assist you with your clinical trial project and offer solutions.

